

THE RESEARCH GRANT PROGRAMS OF THE PUBLIC HEALTH SERVICE

**ISSUES AND CONSIDERATIONS
RELATING TO THE
NINTH REPORT OF THE HOUSE COMMITTEE
ON GOVERNMENT OPERATIONS**

FEBRUARY 1968

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February 1968

U.S. DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

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General

The report issued October 20, 1967, by the Intergovernmental Relations Subcommittee of the House Committee on Government Operations(1) has as its stated purpose "to examine and evaluate the performance of the Public Health Service--especially of its principal research bureau, the National Institutes of Health--in administering grant programs for the support of health research since the Committee's previous reports on this subject in 1961 and 1962." The report sets forth a series of findings derived in large part from staff study, and advocates certain actions expressed in 17 recommendations.

The findings and recommendations embrace a diversity of matters. They concern, on the one hand, such internal administrative considerations as the payment of indirect costs on PHS research projects, the administration of the General Research Support and Health Sciences Advancement Award programs of NIH, the "single instrument" support of the Sloan-Kettering Institute by the National Cancer Institute, and the quality of research supported through NIH programs. On the other hand, they engage the broad problems of equitable distribution of grant support among nonfederal institutions, the nature of national programs and policies aimed at institutional development, and the character and competence of the administration of universities doing research.

The report and its recommendations have been examined carefully at all levels of the Department. This response is the consequence of that examination and represents the Department's considered views and conclusions.

The response is in two parts. The first part sets forth some overall considerations that constitute an essential preface to discussion of the Committee's report. The second part contains the Department's views and intentions in respect to the findings and recommendations of the report. The Department's position on each of the Committee's recommendations is summarized in an appendix.

Part I. Overall Considerations

The Summary Judgment

The Department of Health, Education, and Welfare has the fullest confidence in the leadership of the Public Health Service and the National Institutes of Health. The advancement of knowledge for the health and well-being of man which has been achieved and is being made possible through this country's research support programs in the health and medical research field is surely one of the finest attributes of our national life. To sustain this progress, to enlarge its yield of health capability, and to secure the fullest benefit for the Nation from the public resources utilized are a major and continuing responsibility of this Department.

The framework of organization, functions, policies, and procedures for the administration of departmental grant activities is constantly being unified and strengthened, reflecting an evolution of sophistication, competence, and awareness. The unremitting efforts to advance the effectiveness of this framework is limited only by the ability to recruit in sufficient numbers at the requisite levels of competence and training. Meanwhile, capability at both the constituent and departmental levels to detect and correct administrative inefficiency, ineptness, and irregularity has substantially improved. Thus the Department's response to the findings and recommendations contained in the Committee's report is made in the context of the current status of these affairs.

This process of improvement can only benefit from discerning and fair-minded inquiry, the constructive discussion of findings, and the judicious exploration of recommended courses of action. It is in this spirit that response to the Committee's report has been approached.

PHS Programs and the Growth of Medical Research

It seems both reasonable and pertinent to place the examination of the administration of programs for medical-research support by the Public Health Service and the National Institutes of Health in the context of the changes undergone and the perspective of progress achieved.

In 1956 the total national expenditure for medical research from both public and private sources amounted to \$312 million. The research grant programs of NIH that year involved the support of less than 3,500 research projects with a total budget of about \$40 million. For the Nation as a whole, only about 12,500 senior investigators were at work in some 375

different academic and research institutions. Although the need for new biomedical knowledge was urgent and the latent research capacity of the Nation substantial, national research support programs were severely limited (a heritage of the Korean war and consequent budget restrictions), and only established investigators, research programs, and institutions were being supported.

In the 11 years since 1956, the universe of medical research has been transformed. National expenditures, public and private, now total over \$2 billion. An estimated 65,000 research investigators are engaged in this scientific effort. The research grant programs of NIH now support almost 16,000 research projects, and the health sciences research and training programs of over 2,000 institutions are being assisted. These are some of the dimensions of the current national medical research effort and the research support programs of NIH. They characterize a setting for medical science which, in comparison with that of 1956, is not only of a vastly different order of magnitude, but is beyond equating in respect to the scope and depth of the science involved, the character of the investigators and institutions engaged, and the extent to which national interests are being served.

Thus, the past decade has been characterized by the need for bold policy and program innovation, challenging administrative and organizational adjustments, and extraordinary demands for scientific leadership and managerial skill.

In the development of the PHS research grant program, the effort was made to meet the challenges in such a way as to give clear and dominant emphasis to the achievement of the vital public purposes of these programs without diminishing the provident management of the public funds involved. The record reveals the course of this effort. It shows the energy exerted and the controversy, the strains, the faults that emerged. It also reflects a continual process of modification and improvement directed toward sound program direction and management. But more importantly, it clearly demonstrates the substantial accomplishment and the consequent public benefit that has accrued.

The Basis and Objectives of Change

The transformation of the national medical research scene between 1956 and 1967 derives from the fundamental decision of the Nation to mount and sustain a major effort to gain scientific and technical mastery over the major health problems confronting its people. This decision is expressed in the numerous legislative acts creating the mechanisms and extending the authorities for this effort, and in the acceleration of the funding of medical research through the appropriation process at a pace often exceeding the recommendations of the Executive Branch.

Two major needs determined the courses of action taken to seek achievement of the overall objectives:

1. The base of knowledge and theory relating to the phenomena of life, disease, and health was critically inadequate. Progress in the solution of disease problems demanded substantial enlargement of this scientific base.
2. To provide for this enlargement required not only increased support for the conduct of current science, but purposeful effort to expand the Nation's resources for medical research through training of manpower, construction of research facilities, strengthening of existing institutional research programs, and promotion of additional research capability.

The expanded funding of the NIH programs in the period since 1956 has been administered with the threefold purpose of engendering maximum progress in those critical areas, achieving practical advances in the diagnosis, treatment, and prevention of disease, and accelerating the transfer of this new capability to the universe of health practice.

The Overall Accomplishment

By any measure that can be brought to bear upon the substantive progress of this Nation in the field of the medical and health-related sciences, the accomplishment is impressive. The recent report on the research programs of NIH, prepared at the specific request of the President, (2) notes that the past 20 years of federally fostered growth in health-related science and technology (of which the 11 years since 1956 have been most critical) have--

- revolutionized the range of diagnostic, therapeutic, and preventive capability available for medical and health services;
- transformed the prognostic expectancy in cancer, heart conditions, cerebrovascular diseases, the infectious diseases, problems of mental illness, and many other disease areas;
- opened penetrating insights into the nature of life, the functioning of biological systems, the basic character of disease, degenerative processes, and the conditions of health which provide the basis for the further advance of medical science and practice.

This rich expansion of scientific knowledge and capability has placed the Nation in a position of world leadership in the advance of biology and medicine. Public evidence of this progress is abundant--

- in the volume of newspaper coverage now being given to the work of medical scientists, to basic scientific findings and advances, to achievement in the diagnosis and treatment of disease;
- in the changed character of present-day medicine, its diagnostic and therapeutic capabilities, and the associated hospitals and health facilities;
- in the great university medical centers of the Nation and the complex of teaching, research and service programs they encompass;
- in the world leadership accorded American medical science and the dominance of Americans in the postwar Nobel Prizes in the medical area.

There is general acknowledgement that Federal research support programs have been the single most determinant influence in growth and achievement of U.S. medical science.

Problems Encountered and Generated

The development of NIH programs since 1956 has both encountered and engendered complex and controversial problems, many of which have posed unprecedented issues of public policy. These have required innovative resolutions, often reaching beyond the conventions of current public administration practice.

Over this period of time, the body of concepts, policy, and procedure developed in the conduct of NIH programs has often established the precedents for all Federal programs engaged in the grant support of nonfederal research activity.

But these matters have not been engaged, the resolutions achieved, or the programs mounted without travail. No such process of rapid program development posing such complex issues and demanding such innovative response could be accomplished without error or maladroitness. This circumstance, however, does not diminish this Department's awareness of the need for constant efforts at correction and for continuing improvement of administrative capability.

That such misadventures do not characterize the whole is both the judgment of this Department and the common conclusion of the major external assessments of the NIH programs that have been made, and they are many.

Prior Examinations of NIH Programs

The importance, complexities, and sensitivity of the medical research area and the rapid expansion have led both the Executive and Legislative

Branches of our Government to seek independent assessment of the conduct and accomplishment of this program.

As a consequence, the National Institutes of Health, its programs, and the policies and practices involved in their administration have been submitted to more searching evaluative studies, under Executive, Legislative, and nonfederal auspices, than any other set of Federal research operations. From 1956 to the present, NIH has been the subject of 11 major inquiries:

- Medical Research Activities of the Department of Health, Education, and Welfare (C.N.H. Long Report), 1956(3).
- The Advancement of Medical Research and Education Through the Department of Health, Education, and Welfare (Bayne-Jones Report), 1958(4).
- Federal Support of Medical Research (Boisfeuillet Jones Report), 1960(5).
- Health Research and Training: The Administration of Grants and Awards by the National Institutes of Health (1961 Fountain Report), 1961(6).
- Administration of Grants by the National Institutes of Health: Reexamination of Management Deficiencies (1962 Fountain Report), 1962(7).
- Organization of Public Health Service (Harris-Roberts Study), 1963(8).
- Federal Support of Basic Research in Institutions of Higher Learning (Kistiakowsky Report), 1964(9).
- Biomedical Science and Its Administration (Wooldridge Report), 1965(10).
- Investigation of HEW (Rogers Special Subcommittee Report), 1966(11).
- Report of the Secretary's Advisory Committee on the Management of NIH Research Contracts and Grants (Ruina Report), 1966(12).
- Report of the Commission on Research, American Medical Association (AMA Report), 1967(13).
- Administration of Research Grants in the Public Health Service (1967 Fountain Report), 1967(1).

In addition, the programs of NIH have shared with other Federal research programs the broader reviews carried out by the Elliott Committee, the Daddario Committee, the Harris Committee, the Reuss Committee, etc. Beyond these more or less ad hoc studies, the programs of NIH have annually undergone rigorous review by the cognizant appropriation subcommittees in the House and Senate. The number of pages of the hearings and reports of these committees devoted to NIH is evidence of the scope and depth of the congressional examination carried out in the annual appropriation process.

Two of the recent external studies of the National Institutes of Health were conducted under most distinguished and publicly responsible superintendence. These groups examined in a deliberate and specific manner the quality of the science supported and the consequences of the programs underway. Because of the competence and distinction of these two groups, their summary findings are clearly germane to the question of how well the public interest is being served through the programs of NIH.

1. The Wooldridge Committee Report

The first of these studies was carried out as an official exercise at the direct request of the President of the United States. It was conducted by a committee of distinguished industrialists, university administrators, and scientists over the period of a full year under the chairmanship of Dr. Dean E. Wooldridge. The committee utilized some 12 expert panels comprising about 100 scientists who examined every facet of NIH and its activities. The overall judgment of NIH expressed by this committee in its report to the President was as follows:

"In brief, we consider the NIH program to be sound and recommend its continued support. Its one billion dollar budget is not high, when compared to the more than thirty billion dollars a year the American public pays for assorted health services; the money is on the whole being competently and efficiently employed on a broad spectrum of health-related research; lessons from the past history of science, supported by the current acceleration of medical discovery, strongly suggest a satisfactory future pay-off. Furthermore, as discoveries are made in the life sciences and the physical sciences, new opportunities will be created for health research and these too should be exploited with the enthusiasm and vigor which has distinguished the NIH program during the past decade. We feel that the Congress in particular deserves considerable credit for its past and continuing support of this kind of farsighted program. We suspect that there are few, if any, one billion dollar segments of the Federal budget that are buying more valuable

services for the American people than that administered by the National Institutes of Health."*

"The Committee believes that the current billion dollar budget of NIH is not too high and that it constitutes a sound investment for the American people."**

2. The AMA Report. The second examination was carried out under the auspices of the American Medical Association, at the direction of the Board of Trustees of the AMA, as a basis of declaring the future policy of the Association on the Federal support of medical research. A commission was created in 1964 for this purpose, chaired by the Honorable Charles E. Whitaker, retired Supreme Court Justice. This commission was directed to assess the impact of Federal support of medical research upon the conduct of research itself and upon medical schools, the education of physicians, and the provision of medical services. After a two and one-half year study, the commission's report was published in early 1967. The basic conclusion reached by the commission was as follows:

"We have sought the counsel of representatives of the medical community who have firsthand knowledge of conditions. We have studied the literature of critical commentary. We have drawn upon our own individual experiences and observations. All of this we have done in an effort to discern the truth of conditions in response to the charges given to us. Having sifted through many of the complaints and counter-complaints, we conclude that there is at least some merit to all of them, yet we also conclude that on balance the public has benefited immensely from the total effort in medical research which largely has been carried out since World War II under the aegis of the National Institutes of Health.

"In saying this, we do not deny that the growth of the national commitment to medical research has been attended by serious problems. To the contrary, many problems can be identified. This is normal--an expected fallout of progress. The challenge is not whether problems ought to be avoided--for this would be hoping for too much--but whether medical leaders and Federal administrators are able to cope realistically and constructively with them in the broadest public interest."***

*Reference 10, page 7.

**Ibid., p. 6.

***Reference 13, pages 26-27.

The findings of the study were, on the whole, favorable to NIH and, on such critical matters as the quality of its research programs and their impact upon medical education and services, entirely supportive. As reflected by the above excerpts, the commission noted stresses and strains as well as imbalances in the development of the Federal support. These, the commission considered to be an inescapable part of the evolution of a massive and complex set of activities.

Study and examination of the kind carried out by the above groups can help to provide a basis of judging the overall effectiveness of NIH programs. In general, the judgments reached by all the groups concerned with the consequences of NIH programs, as well as their administration, have not only been favorable but strongly supportive of NIH, while at the same time providing constructive advice for continuing improvement.

PART II. SPECIFIC FINDINGS AND RECOMMENDATIONS

The Effort to Improve the Management of Grants

The Committee notes that its examination of the research grants program of the Public Health Service and the National Institutes of Health discloses that "relatively little effort" has been made to improve the management of grants since the previous reports of the Committee in 1961 and 1962.

The effort to improve and strengthen the administration of research grants within the programs of PHS and NIH is continuous. The sequence of events since the inception of these programs in the late 1940's reflects progressive actions toward this end. Without question, the reports of the Committee on Government Operations for 1961 and 1962 gave substantial impetus and direction to this process. Since 1962, numerous major actions have been taken within NIH and PHS and at the level of the Office of the Secretary of Health, Education, and Welfare to further the process of strengthening the administrative aspects of grant programs. * Many of these actions have had substantial impact upon the administrative processes of grantee institutions and the activities of the supported investigators. At the same time, NIH, PHS, and HEW have contributed to and been affected by broader government-wide efforts to advance the management of Federal grant programs under the guidance of the Federal Council on Science and Technology, the Office of Science and Technology, and the Bureau of the Budget.

In very large part the organization, policies, procedures, and patterns of action in the area of grant management in NIH, PHS, and HEW have been transformed since 1962 as a consequence of progressive efforts toward improvement. These efforts have included:

- the complete overhauling and strengthening of the organizational and functional framework for grant management reaching from the Institutes and Divisions of NIH through PHS to the Office of the Secretary of HEW;
- progressive and selective expansion of the number of personnel assigned to both the program and administrative aspects of grant activities, including the initiation of a specially designed training program for such staffs;

* Progress in the development of grant management capability and the improvement of the departmental function relating to grant policy, financial management, auditing, and institutional relations is set forth in "A Report to the Secretary on Progress in Financial Management" by the Assistant Secretary Comptroller in October, 1967. (Copies available.)

- the development and issuance of manuals of policy and procedures regularizing and codifying the principles and practices of grant management by both the granting units and the grantees; (14)
- the development and publication of regulations governing the exercise of the basic grant authorities;
- centralization of the process of indirect cost determination at the departmental level;
- the development and installation of systems governing grant payment to improve the cash outflow position of the Government in this process;
- the consolidation of external grant audit functions at the Department level;
- the conversion of data-processing activities relating to grant applications and awards and the process of review and approval to a computer-based system, greatly extending grant data capability;
- inauguration of a pilot study to extend and strengthen the managerial responsibilities of grantee institutions as a basis for advancing generally the role of grantee institutions in the management of grant funds;
- delineation of the role of advisory councils in the conduct of grant programs to improve and clarify the processes of program development and program execution.

As a consequence of these and many other actions, the Department's arrangements, and particularly those of PHS and NIH, are substantially different and materially improved over the setting examined by the Committee in 1961 and 1962. Since 1965 the Department's role in the progressive advancement of grant management capability has been functionally elaborated through the establishment of a Division of Grant Administration Policy, the centralization of audit and indirect cost functions, and the coordination of fiscal and budgetary procedures.

To assist in the further development of sound grant policies and improved grant administration in grantee institutions, the Secretary recently established a Grant Administration Advisory Committee made up of representatives from all sections of the DHEW grantee community. Through this mechanism communication with nonfederal institutions can be improved. This exchange will extend greater awareness of the condition of public business to grantees and provide insight on the part of Federal administrators into the problems and needs of institutional management.

Thus positive development has taken place in the administration of grants in the PHS and throughout the Department, and the process is a continuing one. Additional changes in these overall arrangements, both in process and projected, will be noted in subsequent sections of this response as appropriate.

It should be clear that there is no lack of diligence and intent on the part of this Department and its constituents to achieve high management standards in grant administration in the conduct of its programs. DHEW administers more grant programs and expends more Federal funds through the award of grants than any other Federal agency. There is no disagreement with the Committee in respect to the responsibility for sound management that the administration of these programs demands.

Indirect-Cost Overpayments

The Committee states that the Public Health Service continued to make a provisional allowance of 20 percent for indirect costs in grant payments until 1965 without regard to existing indirect-cost rate determinations. This practice, the Committee finds, resulted in unnecessary overpayment of grant funds and consequent additional expense to the Government in obtaining repayment and generated friction between the granting agency and the grantee. In addition, the Committee cites the payment of indirect costs at rates established for on-campus activities for research projects conducted wholly or partly off campus.

In regard to these matters, the Committee proposes in its Recommendation No. 1--

" . . . that the Surgeon General make suitable arrangements to assure the uniform application of the Department's indirect cost rate information by all granting units of the Public Health Service. With respect to the use of off-campus rates, which are normally lower than on-campus rates, the committee recommends that the Public Health Service obtain sufficient information in grant applications and in subsequent reports to identify the locations at which the research is performed."

The problems surrounding the determination of indirect costs, their method of calculation, the allowable items, and the appropriate share of Federal responsibility for such cost have constituted some of the most complex and disputed aspects of the Federal support of research in nonprofit institutions through grants. The background of these problems and the subsequent actions in respect to them are relevant to the events criticized by the Committee.

In fiscal year 1958 the Congress first established a statutory limit on the percentage of the direct costs of research projects that could be paid for the associated indirect costs. (15) The limit set, 15 percent, had no particular basis in fact other than being the current allowance for indirect costs established administratively by the Public Health Service. It was at the time, however, that academic research activities were in the initial stages of the tremendous post-Sputnik expansion with which the increased support of medical research coincided. Research as a university function was being transformed from a subordinate to a major and, in some instances, dominant role. This process generated accelerating demands upon the central administrative and service structure of these institutions, along with related incremental costs. In many instances, there were substantial diversions of basic institutional resources to enlarge the structure of central facilities and services to meet these expanding needs. This

changed in a fundamental way the previous pattern of direct-indirect cost relationships, rendering past measures meaningless and introducing a protracted instability into such determinations.

The above set of circumstances generated widespread concern among grantee institutions over the effect of statutorily fixed percentages for indirect costs in the face of expanding Federal research expenditures and limited institutional resources. Thus the national scene prior to the elimination of the statutory limits on indirect cost rates was dominated by the pleas of institutions that their capability to support their non-science functions was being diminished because of the failure of Federal agencies to pay the full overhead costs of federally sponsored research. (16) Numerous studies of this problem supported the view that a complex and serious issue was presented by the then existing national policy. (17)

The available information indicated that the gap between the statutorily fixed rates and the actual indirect-cost rates was substantial. This discrepancy was emphasized by a study of the indirect-cost experience of a representative sample of colleges and universities conducted in 1960 by the National Science Foundation and published in 1962. The report stated:

" . . . The national weighted average of indirect cost rates was 28% of direct costs for large colleges and universities (those receiving over \$250,000 in grant funds) and 32% for small colleges and universities (those receiving less than \$250,000 in grant funds)." (18)

Overhead rates emerging from university contract activities of the Department of Defense ranged from 26 to 67 percent of salaries and wages, with a median of 40 percent or approximately 26 percent of direct costs. The experience of the National Aeronautics and Space Administration showed indirect costs emerging as 28.8 percent of direct costs. While these numbers are only illustrative, they do serve to emphasize the pervasiveness and reasonableness of the existing view that actual indirect-cost rates were substantially above the statutory limitations then imposed. Thus in these early years, from 1958 to 1962, NIH awards included a flat indirect cost allowance equal to 15 percent of direct costs.

When the statutory ceiling on indirect costs was increased to 20 percent with the further limitation that the rate paid should not exceed actual costs, the risk was still considered to be minimal, and provisional allowances of 20 percent were made where rates were not available.

The problem of determining indirect-cost rates was complicated by a series of other circumstances, which, despite the Committee's opinion to the contrary, were not amenable to simple and rapid resolution:

- Valid, current indirect-cost rates clearly applicable to PHS grants were not available for many institutions. (PHS provides grant support to over 2,000 institutions, whereas the DoD "Tri-Service Master List" of indirect-cost rates, even as of July 1, 1966, covered only 190 institutions. For only 144 of these 190 were the rates based on cost data less than three years old.)
- Where DoD rates were available, many were derived from conditions substantially different from those surrounding the PHS support of research and thus were not immediately and directly applicable. [As an example, the DoD rate for one institution was 12 percent of salaries and wages only (and based on a single contract), whereas the actual audit of costs resulted in a rate of 21 percent of total direct costs applicable to PHS grants.]
- In contrast to the DoD contract relationship, PHS has no authority to make supplemental grants to cover underestimated costs after the completion of a project. To avoid penalizing institutions, the provisional allowance in the initial award must be sufficient to cover probable costs where firm rates are not available. The grantee institution in the grant relationship has no right of recovery, whereas the Government does.

In the context of these circumstances, the award of grants utilizing the full, statutorily authorized indirect-cost allowance of 20 percent on a provisional basis pending development of an appropriate rate seems a necessary, expeditious, and because of the prevailing view of the inadequacy of the authorized limit, safe and fair procedure. In no sense was there an intent, nor were the arrangements devised, to pay institutions more than their actual indirect costs as determined by audit.

The events which are the basis of the Committee's criticism emerged from the following circumstances:

1. In a limited number of instances, the actual indirect-cost rates turned out to be less than the provisional allowance of 20 percent. Thus this arrangement did result in some overpayments, and the amount in the case of one institution was substantial. * The following data, however, provide a better sense of the context in which these provisional allowances were made. In fiscal year 1966, there were 127 institutions which individually received a total of \$1 million or more in research grants. The amount of money awarded to these institutions totaled, in the aggregate, \$529 million, or 81 percent of the \$655 million in PHS research grants awarded to all institutions. None of the 127 institutions had direct-cost-based overhead rates of less than 20 percent.

*Overpayment of indirect costs to Health Research, Inc., for which full explanatory details are given in Part A of the Appendix.

2. The complexities surrounding the establishment of rates and their application to particular research projects revealed the need to improve the then existing PHS arrangements and procedures to deal with this problem.

3. The complexity and diversity of the nonfederal institutional framework and its operational and administrative patterns presented a series of unusually complicated problems surrounding (a) the over-head entitlement of "legal third parties" (e.g., Health Research, Inc.); (b) the distinctions between "on-campus" and "off-campus" research and appropriate rates for these; and (c) the determination of the proper and legal recipient of indirect-cost payments.

Prior to the Committee's inquiries into these matters in its hearings of June 1965, the National Institutes of Health had already initiated a series of modifications to improve the development, dissemination, and application of indirect-cost rates:

- Provision for additional information concerning the location of the proposed research activity was added to the application form.
- The PHS responsibility for the negotiation and dissemination of rates was centralized in the Financial Management Branch of NIH.
- An Indirect Cost Register was established as the central source of this information.
- Rates were listed for 1582 of the 2086 institutions comprising the universe of PHS grantees prior to the transfer of this function to the Office of the Secretary in August 1966.

In December 1964, NIH institutes and divisions were provided with an indirect-cost register containing rates for over 400 institutions and were instructed to compute indirect costs at the listed rate or 20 percent of total direct costs, whichever was the lesser. Working arrangements were set up with the Department of Defense and the National Science Foundation whereby the rates developed by each agency are utilized by all. In December of 1965, the PHS issued a directive that no funds for indirect costs would be allowed those institutions that failed to submit an indirect-cost rate proposal by March 1, 1966.

In August of 1966 responsibility for the negotiation and original dissemination of information on indirect-cost rates and the establishment and clarification of policy in this area were centralized in a newly created Division of Grant Administration Policy in the Office of the Assistant Secretary, Comptroller of DHEW. This step ensures unified departmental action in the determination of indirect-cost rates, common policy in respect to application throughout the Department, and coordinated resolution of related problems. The Indirect Cost Register

set up by NIH, as supplemented by the Division of Grant Administration Policy, continues to be the basic source of information in this area. Intra-departmental liaison on indirect-cost matters has been centered in the framework of financial management offices of the constituent and bureau levels of the Department. In those instances where careful examination reveals actual overpayment of indirect costs, appropriate collection action is being taken.

Thus, in respect to Recommendation No. 1 of the Committee's report, the arrangements proposed therein have already been accomplished. A system to assure the availability of indirect-costs information and uniform policies in its application throughout DHEW has been established. Provision has been made for securing additional information on the location of research activities, to assist in ascertaining the application of differential off-campus indirect-cost rates.

Despite the progress in this area, the handling of indirect costs continues to present policy and operating problems which are now under study to permit further improvement:

1. Because of the varying sources and currency of indirect-cost rates, and the varying character of research projects, available rates may not be directly and simply applicable, presenting continuing problems to program administrators involved in determining the amounts of awards.
2. Increasing costs and the changing administrative arrangements in institutions limit the durability of a given rate and the extent to which use can be made of the fixed-predetermined rate method of paying indirect costs authorized by P.L. 87-638. This forces continuation of the process of making provisional allowances for indirect costs, with the consequent burden of recalculations and adjustment. The Department is endeavoring to extend use of the fixed, predetermined rate method in administering indirect-cost activities; but frequent audits will still be required to establish the validity of a prior year's rate as the basis for setting a forward rate.
3. The determination of the appropriate circumstances for the use of "off-campus" indirect-cost rates can be extraordinarily complex. Various factors enter into whether an off-site rate should be used. For example, where an investigator and staff engage in a research project involving substantial time in a Veterans Administration hospital or other off-site location, but also occupy office and laboratory space at the grantee institution, there is a question whether an off-site rate should be used. Moreover, Bureau of the Budget Circular A-21 provides that a rate separate from the overall, institutional indirect-cost rate should only be utilized when there is a segment of research activity within an institution to which a

significantly different indirect-cost rate would apply and when the volume of such research is material in relation to other Government research at the same place. A specific study is now underway aimed at developing criteria for establishing off-site rates and the mechanics for identifying the circumstances where such rates should be applied.

Improving Indirect-Cost Determination

The Committee report notes the progress made in the development of a comprehensive audit program within DHEW and endorses its goals. The report expresses the Committee's concern over the absence of unified auditing arrangements for the Federal Government as a whole. This, the report states, would be beneficial not only to the Government but also to the institutions being supported. The report reviews some of the interagency efforts aimed at developing a single-agency approach to the establishment of indirect-cost rates for institutions of a given type.

As Recommendation No. 2, the Committee--

". . . endorses the concept of assigning Government-wide responsibility for establishing indirect cost rates with all institutions of a given type to a single Federal agency, with each type of institution audited by one Federal agency only. The committee recommends that this concept be vigorously pursued by the Bureau of the Budget and other interested agencies so that a final Government-wide plan covering all institutions will expeditiously be established."

While deferring to the primary responsibility of the Bureau of the Budget in respect to Recommendation No. 2, it should be noted that the Department has long advocated this objective and sought to engender its exploration. Thus DHEW is in full accord with this recommendation.

General Research Support Grants

The Committee report states that the Committee has made only a limited study of the General Research Support Program. It is nonetheless sharply critical of the conduct of that program. Based on its examination of awards involving four nonacademic organizations,* the Committee found the policy and procedures of the program to be inadequately developed for the equitable and uniform treatment of grantees, and the premium given for nonfederal funds under the General Research Support formula, difficult to administer and wasteful of Federal research money. The opinion is expressed that this premium did not operate as a meaningful incentive to private research support, that it favored research organizations over institutions of higher education, that it favored wealthier over poorer institutions, and that it produced an obvious distortion of the purpose for which the GRS legislation was enacted, since the program was primarily intended for institutions of higher education.

In respect to these matters, the Committee offers--

"Recommendation No. 3-- . . . that program policies be changed immediately to:

- (1) Determine each GRS grant on the basis of the recipient institution's research expenditures from Federal sources alone. The committee does not believe the premium given for non-Federal research funds under the existing formula operates as a meaningful incentive for institutions to seek private funds. Rather, this premium favors research organizations over institutions of higher education, and has been difficult to administer and wasteful of Federal research money, and
- (2) Exclude from the computation base for a GRS grant all Federal payments for research which include fees above actual research costs."

The legislation providing the authority for the General Research Support program was enacted by the 86th Congress and signed into law on September 15, 1960 (P.L. 86-798). The overall purpose of the legislation was to authorize the provision of funds to educational and research institutions "to assist in the development and maintenance of a sound, well-balanced program of research and research training in medical, dental, public health, and related areas without specification of the precise research and research training activities to be undertaken with the grant funds." (19)

* The award to Health Research, Inc., of New York State was particularly criticized. For an explanation of this matter see Appendix, Part B.

In other words, the basic objective being sought in this legislation was to provide additional means to extend the national effort directed toward disease and health problems and not the support or strengthening of institutions as such. Thus, the programs developed under this authority were to be as mission centered as the programs providing project support, however general the mechanisms of award might be.

It is important to note, in respect to the Committee's view that programs developed under this authority were to be directed toward medical schools and other academic institutions, that the law specifically authorizes such grants-in-aid not only to "public nonprofit universities" but also to "hospitals, laboratories and other institutions." Furthermore; in respect to subsequent discussion in the Committee report and in this response relating to the legislative authority of the Health Sciences Advancement Award, the legislative intent to provide broad authority permitting continued evolution of programs to meet future emerging needs is clearly conveyed by the following statement in the House Committee Report:

"Following the legislative pattern upon which the project grant programs of the Public Health Service have been developed, the proposed amendment is couched in general language so that the scope and terms of the institutional research support programs (underscoring supplied) can be developed on the basis of operating experience and can be adapted to the evolving needs of our national research effort." (20)

The implementation of the GRS program was carried out under a directive from President Dwight D. Eisenhower. (21) Among other things, this directive set forth in general terms the principles to be observed in distributing GRS funds, including a basis for defining eligibility and for eliminating disproportionately large claims by any single institution. Explicit instruction was given to administer this program so as to provide incentives for the increase of contributions for medical research from nonfederal sources. These general principles led to the development of a formula for allocating the total appropriation made by the Congress among all eligible applicant institutions.

This formula simply is the mechanism for distributing funds according to the principles underlying the GRS program and the directives promulgated for its administration. The policy of including expenditures for research from nonfederal sources as claims for entitlement to GRS awards, and of attaching a premium (funds from nonfederal sources are given twice the weight of Federal funds in the formula) to such expenditures, was a consequence of the legislative history and the executive directive pursuant to which the program was initiated. This directive, among other things, stated explicitly:

"In the administration of P.L. 86-798, approved September 15, 1960, I direct that the following guidelines be applied . . .

5. The authority contained in the law should be administered to provide specific incentives for the increase of contributions for medical research from nonfederal sources." (21)

The NIH has devoted considerable attention to an examination of many problems posed by the premium on non-Federal expenditures, and has concluded--with the Government Operations Committee and with the NAS-NRC Committee that reviewed the GRS program in 1964-1965 (22)--that the premium does not provide an effective incentive to nonfederal support of medical research. This premium policy has also been most difficult to administer. As a consequence, the view of the NIH is consonant with the Committee's--that the entitlement base for GRS grants should be limited to expenditures from Federal sources.

The Committee's report also states that this premium element in the formula "was wasteful of Federal research money." In this connection, it should be noted that the premium in the formula exerts its influence only on the distribution of a fixed appropriation among eligible institutions. That some institutions may have received more or less than what might be considered from other points of view their proportionate share does not, ipso facto, mean that Federal funds have been used by the recipients for purposes other than those for which the program was developed and thus "wasted." While misallocation is, under no circumstances, to be condoned, and while determined effort has been made to avoid it, the Department suggests that a distinction be made between "misallocation" and "wastage" in this respect.

The force of the Committee report's statement that the premium in nonfederal funds favors wealthier institutions over poorer ones is not entirely clear. As noted above, the formula for computing a GRS award properly yields an amount in proportion to the magnitude of the grantee institution's research expenditures made from funds--federal or non-federal--received under terms which restrict their use to research. Thus, up to the prescribed ceiling, the formula rewards institutions in proportion to their commitment to health-related research. As such the program is intrinsically discriminatory in operations, and must be so if the intent of the program is to be met. It would be more accurate to state that the premium on funds from nonfederal sources has favored institutions which have succeeded in reducing their dependence upon Federal funds in the execution of a valuable public service, the conduct of health research.

NIH will soon complete a detailed examination of the impact of eliminating nonfederal expenditures as a basis for entitlement for GRS awards. Possible approaches for attenuating the adverse consequences

of the change are being considered. Upon completion of this review, the Department plans to seek a modification of the relevant administrative guideline promulgated by the President in 1961 and followed since that time.

Thus, in respect to Part 1 of Recommendation No. 3 of the Committee report, the Department has directed the Public Health Service and the National Institutes of Health to submit to the Secretary a plan for modification of the formula used in calculating the awards under the General Research Support Grant program. This plan will provide for the elimination of the premium factor for nonfederal research expenditures, as well as other changes considered desirable. This plan will also encompass such interim arrangements as may be necessary to moderate abrupt changes in the magnitude of grants now being received by institutions whose entitlement may be substantially affected by the revised formula.

The Committee notes that the policies for the General Research Support program do not exclude from the grant computation those expenditures under Federal research contracts, the terms of which include a fee above actual cost. In its comments on this point, the Committee apparently assumes that all fees included in the terms of Federal research contracts are equivalent in purpose to the General Research Support grant--that is, that they are allowed in recognition of the desirability of supporting the self-sponsored research activities of the contract recipient.

Although such fees may on occasion serve such a purpose, this is not the basis on which the fees are awarded. The Federal Procurement Regulations concerning the negotiation of fixed fees for research contracts describe a number of factors which are to be taken into account in the negotiation of such fees. The institution may use the fees, once earned, to meet any of the needs of maintaining the institution. There is no way to determine whether the fees were used for interest payments on indebtedness, to cover losses on contracts, for fund-raising activities, applied toward building construction costs, used as operating capital, for self-sponsored research, or for other needs of the institution.

Since NIH is neither in the position to verify the specific limitations placed on fees in research contracts from other Federal agencies, nor to verify expenditures made by institutions from such fees, it would appear that the simplest resolution of this matter would be to exclude all such contracts from the General Research Support base.

Thus, the Department concurs with Part 2 of Recommendation Number 3 and has issued instructions to the Public Health Service and the National Institutes of Health to exclude from the formula basis for calculating a General Research Support award all Federal research

contract funds which include fees above actual research costs. The amount of specific fees on such contracts are, under present policies, excluded from the entitlement calculation. In view of the Committee's concern of the data furnished in respect to the Stanford Research Institute, PHS and NIH have also been directed to take appropriate action to the extent that applicable policy and practice in respect to contract fees have not been observed.

Health Sciences Advancement Award

In discussing the Health Sciences Advancement Award (HSAA) program, the Committee found that the first awards under this program were made (1) without adequate study of the needs of various types of institutions for development funds; (2) without careful formulation of program objectives and policies; (3) without a prior public announcement of the new program and its eligibility conditions; (4) without open competition for the available funds; and (5) without clear statutory authority. Moreover, the Committee contends that NIH's recent handling of the second group of HSAA awards leaves the purpose of this program still unclear.

Program Initiation. The committee characterized the procedures employed by NIH in the initiation of the HSAA program as "irresponsible; unscientific and contrary to the best interests of the academic community and the Government." Four recommendations were made as follows:

"Recommendation No. 4--The committee strongly recommends that no future grant programs be initiated by NIH or the Public Health Service without fair and open competition after the purpose and the policies of the program have been carefully developed and publicly announced.

"Recommendation No. 5--The committee further recommends that before any new grant program is started, or a major change is made in an existing program, the proposed regulations for the program be published in the Federal Register so that interested parties may have an opportunity to express their views. The final regulations should be approved by the Secretary before issuance.

"Recommendation No. 6--The committee recommends that before any new program is initiated in the Public Health Service without specific statutory authorization, the program should be formally reviewed by the Department and the Executive Office of the President to determine its conformance with national education and science policies. Also, a written opinion concerning the legality of any such program should be obtained in advance from the HEW General Counsel.

"Recommendation No. 7--The committee further recommends that no additional HSAA awards be made unless and until PHS obtains specific legislative authorization for this program."

As a matter of general practice, vigorous open competition governs awards of the funds appropriated to NIH for research project grants, training grants, fellowships, and facilities construction grants.

Programs such as these, once well established, published statements describing their objectives, eligibility requirements, application formats, and the process for review and approval. When features distinctive enough to require amendment of the PHS regulations emerge, the prescribed formalities, including publication of contemplated changes in the Federal Register, are observed.

Thus, NIH has long respected and prized the tradition of public administration that gives all potentially eligible claimants equal access to appropriated funds. In the administration of NIH Research Grant programs, elaborate machinery has been developed over time for informing potential applicants, for the filing of applications, and for subjecting these to careful review according to clearly understood criteria of scientific merit and program relevance. But it is important to note that this widely known and respected framework emerged only after considerable experimentation and progressive modification based on experience. Throughout this period new program developments were initiated in limited trial forms as a basis for assessing the validity of the concepts involved and the procedural adaptation required. From such tryouts the basis for broader efforts and the information required for adequate public announcement were formulated.

This modus operandi has been typical of the administration of NIH programs. It seemed clear, after careful consideration, that the best interests of the Government and the academic community would be served if a similar approach was exercised in the experimental phases of the HSAA program. That there was extensive consideration and study of the needs to be served and objectives sought is reflected by the series of events that preceded the initiation of the experimental phase of this program.

By 1964, consensus had been reached, both within high echelons of the Government and among distinguished academic scientists and administrators, that the long-term strength of this Nation, and the capability of its science and technology to remain competitive and responsive to the aspirations of its citizens in an age dominated by science and technology, were critically dependent upon the broad upgrading of its institutions of higher learning. Highest priority in this endeavor was widely assigned to the development of new centers of excellence in research and research training. The Report of the Seaborg Committee to the President's Science Advisory Committee is illustrative:

"Basic research and graduate education, together, are the knotted core of American science, and they will grow stronger together or not at all.

"In the advancement of science the best is vastly more important than the next best. . . . Equally with the importance

of sustaining what is already outstanding, we urge the importance for the country of an increase in the number of universities in which first-rate research and graduate teaching go forward together. The growth of science requires more places with superior faculties and outstanding groups of students. Existing strong institutions cannot fully meet the nation's future needs. . . . Timely and determined support to the rising centers will be repaid many times over in service to society. . . . Over the next 15 years the United States should seek to double the number of universities doing generally excellent work in basic research and graduate education." (23)

The consensus typified by this quotation was not reached casually by either government officials or private citizens. It represented the distillate of careful studies, searching questions, and profound discussions by some of the wisest and most public-spirited citizens of the Nation.

Equally clear was the fact that money, while necessary, would not alone be capable of converting average or unevenly balanced competent institutions into broadly distinguished ones. Indeed, careful appraisal of the history of the evolution of academic institutions in the United States over the last few decades suggested that much had to be learned before NIH could confidently commit major fiscal resources to programs of this character in the area of the health sciences. The Kistiakowski Report had recommended that before programs of institutional development were started on a large-scale, a competent special task force be assigned responsibility for studying principles and criteria for such awards. (9)

NIH, having participated actively in the Discussion Group on Government/University Relationships,* which had met during the fall of 1963 and spring of 1964, felt that further discussion in the abstract would not be a profitable investment of time or effort and would only postpone desirable action. Instead, an experimental approach in the health sciences appeared to NIH to be more useful and practicable. This could be undertaken in cooperation with institutions which seemed to present not only problems that were fairly typical of a class of potentially eligible institutions, but also opportunities that promised a high return of information from such investment. The results of a pilot program of this sort could be expected to define more sharply the classes of institutions most appropriate, the nature of the activities most desirable to support, the significance of award size and duration on the effort achieved, and the problems associated with attempting to exert a catalytic influence--that is, the use of the NIH award as a minor presence, yet one which accelerated a far larger process of improvement.

* An informal discussion group meeting under the aegis of the Office of Science and Technology.

Initiation of such an experiment on a small-scale basis appeared to be an approach that would lay the groundwork for a soundly conceived formal program when and if expansion on a national scale could be justified. After first-hand experience had been garnered, program objectives as well as the policies and procedures for attaining them could be defined in terms of greater precision and specificity than those general ones which were the best possible within the existing state of knowledge. The rationale for establishing the eligibility requirements for various classes of institutions would also become more evident.

An important consideration related to the possibility that a program of the sort envisaged would not lead to the goals sought. In the event that the feasibility study did not yield encouraging results, a pilot program launched cautiously, pragmatically, and without extravagant promises could be terminated before large sums of money had been committed. For while large awards to potential "centers of excellence" might turn out to be useful to the grantee and to the Nation in important ways, they would only be justifiable under this program if they produced the "quantum" increase in capability required to establish a true center of excellence in the health sciences.

Furthermore, the articulation of a proposal for the use of funds for significant institutional advancement would require applicant institutions to make a searching review of their present status and future plans, to delineate the goals and objectives toward which their institutional destinies would be directed, and to make their HSAA proposal congruent and integral with these plans. This is a major undertaking for any university, costly in terms not only of money but also of the time and energy of its faculty, if properly and seriously executed. To attract a large number of institutions into embarking on such an exercise, when the funds available were barely sufficient for an experiment on a very small scale (2-4 awards during the first year), seemed tantamount to raising false hopes (and when these were dashed, as inevitably most would be, to inviting enmity) and to encouraging on a major scale an investment of university funds, energy, and time that would, at least in the short haul, be almost totally unproductive.

The specific impetus that led to the beginning efforts in this program was the direction contained in the FY 1965 Senate Appropriations Committee Report (No. 1460) dated August 17, 1965:

"The committee would also like to see--within this funding level--a start at least made in 1965 in the use of general research support grants for institutional development purposes. The committee has heard much testimony on the need

to bring existing institutions to fuller realization of their potential for research excellence in the full complement of the sciences related to health research, with some regard also to suitable geographic distribution of these institutions. There is need, for example, to fill out broad areas of deficit in otherwise fairly complete programs." (24)

Following on this Congressional expression, and with the considerations set forth above in mind, the decision was made to inaugurate this program--

- by staff negotiation with and selection of a small number of candidate institutions;
- by staff assistance in the preparation of applications, an activity related to the fact that the awards were intended to be experimental and to yield information to be used by the NIH in program design;
- by review, seriatim, by an ad hoc preliminary review committee and the National Advisory Health Council.

Under the circumstances operating in the inauguration of the HSAA program, this procedure was deemed to meet what was considered to be the operating imperatives and appropriate respect for the best interests of government and, in this case, academic institutions. Clearly the few institutions initially selected for participation were advantaged, but in the long run it was felt that the program which evolved out of the experiment would be far more fair and equitable to the total universe of eligible institutions.

Why four institutions were selected for the beginning negotiations and not six or eight from which the final choice could have been made, was basically a question of what was considered feasible and practicable in terms of the time available and the staff work required. In retrospect and from a broader viewpoint, it probably would have been better to have provided for a larger degree of choice in making the final selections for this beginning program.

Nonetheless, the Department is persuaded that the conditions which prevailed at the time justified NIH's exercise of limited experimental option, even though the number of institutions involved might have been larger. Beyond undertaking what amounts to pilot efforts under appropriate terms, the Department concurs fully with the general procedure advocated implicitly and explicitly in the Committee's report: that new formal programs be inaugurated after public announcement and with open competition.

Therefore, the Department's reaction to Recommendation No. 4 is concurrence in general, but with clear recognition that under exceptional circumstances, such as those prevailing at the time the HSAA program was inaugurated, the constituent agencies of DHEW must be permitted the flexibility under appropriate Departmental guidelines to experiment with imaginative and creative program innovations so essential if national needs are to be responsibly served.

The acceptability of Recommendation No. 5--for the publication in the Federal Register of the proposed regulations for new programs and the major changes in regulations for existing ones--depends on the definition of "new" and "existing." The Department would have no objection to supplementing the highly effective public announcement procedures traditionally employed by NIH with use of the Federal Register when it has been determined that new programs (1) have completed their experimental phases, (2) have encountered and solved the major administrative problems that usually appear during early operational phases of novel endeavors, and (3) have been expanded to a significant scale. Until such time, an agency needs maximum flexibility to be responsive to unexpected situations, and needs freedom from ponderous and formalistic procedures in order to modify policy rapidly in the light of lessons taught by operating experience.

The use of standing and ad hoc advisors and advisory committees, and of National Advisory Councils, has been a very effective mechanism for soliciting the opinions and the reactions of interested parties. In the same context, major changes in existing programs--when important, widely applicable, based on extensive experience, and viewed as relatively permanent--should also be published in the Federal Register. Standard procedure, of course, requires the Secretary to approve and issue such regulations.

Statutory Authority. The concerns of the Committee on this score take two forms: a challenge of the adequacy of existing authority, with the implication that administrative actions taken by NIH in starting the program were illegal; and an insistence upon the need for explicit statutory authorization for the HSAA program.

The legislative history of Public Law 86-798, which authorized grants for general support of the research and research training programs of certain classes of institutions, clearly envisaged the broad exercise of discretion in the design of detailed instruments to carry out the purpose of the law. Thus, the Report of the House Committee on Interstate and Foreign Commerce (House Report 2174, 86th Congress) accompanying H.R. 10341, published August 26, 1960, states:

"Following the legislative pattern upon which the project grant programs of the PHS have been developed, the proposed amendment is couched in general language so that the scope and terms of

the institutional research programs can be developed on the basis of operating experience and can be adapted to the evolving needs of our national research effort." [Emphasis added.] (20)

It was in this context that the Health Sciences Advancement Award was conceived, and there was no question within the Department that it was clearly covered by the existing general-research-support authority. However, the adequacy of the statutory authority for the program was challenged in the spring of 1967 in the process of examination by the Committee on Appropriations of the U.S. House of Representatives of the President's budget requests for fiscal year 1968. As a result, first the Office of the General Counsel for the Department of HEW and then the Comptroller General of the United States were requested to rule on the question of adequacy of the existing legal authority to operate the Health Sciences Advancement Award program. Each of these offices affirmed that the authority conveyed in the General Research Support statute (P.L. 86-798) was adequate for the action taken. (25, 26)

The Department, as a consequence of these opinions, believes that the requirement of specific statutory authorization for the HSAA program has been met. Thus Recommendation No. 7, which is predicated on a contrary assumption, must be considered inapplicable.

The Department agrees with the objectives inherent in Recommendation No. 6, that a new program should be "formally reviewed by the Department and the Executive Office of the President to determine its conformance to the national education and science policy." The formal process of the development of the budget requests requires both program examination and concurrence by the Department and the Bureau of the Budget. Thus it may be reasonably inferred that this program was in "conformance with national education and science policies."

The recently adopted Planning-Programming-Budgeting System (PPBS) will enhance the capability of the Department to exercise its judgment and influence on new programs. On the more general issue of legislative authority, the Department agrees with the Committee that wherever the adequacy of existing authority is in reasonable doubt, a formal ruling should be sought on this question.

Single-Instrument Support: The Sloan-Kettering Award

The Committee report notes the conversion of NIH project support of research and training activities at the Sloan-Kettering Institute for Cancer Research in New York City to a single cost-sharing grant providing long-term support at annual amounts ranging from \$4.4 million to \$4.7 million, representing 47 percent of the institution's total operating budget. The Committee expresses concern over the policy implications and operational consequences of this action. In particular it cites problems of scientific and administrative review of such an arrangement, the withdrawal of a sizable sum from the competitive project system, and the consequent loss of access to objective outside judgment of the scientific work involved. The Committee also questions the broad discretionary authority available to the Public Health Service under which the grant was made [Section 301(i) of the PHS Act] and proposes in Recommendation No. 8--

" . . . that the Congress amend this provision of the Act to clarify and limit the Surgeon General's authority to adopt 'such additional means as he deems necessary or appropriate' for the conduct and support of research."

Cancer is among the most dreaded of health hazards. It is second among the principal causes of death. Its form and manifestation as a disease is both diverse and manifold. Its basic cause is unknown and therapeutic capability to forestall or modify the disease is piteously limited. The scientific obstacles to the achievement of greater control are enormous, since the pathologic process involves the most fundamental and intricate mechanisms of the exchange of matter and energy at the cellular level. Many of the broad problems in cancer are not amenable to solution by individual and independent scientists. Rather, they require the interdigitation of many discrete scientific skills, at both fundamental and applied levels, under some general plan of attack. Since the creation of the National Cancer Institute in 1937, every effort has been made to advance a massive and meaningful scientific attack upon this problem.

Hence, one of the principal objectives of the National Cancer Institute in recent years has been to increase the number of research institutions with complete concentration upon cancer research and to facilitate and sustain the development of cohesive and comprehensive scientific programs in this area.

The cultivation of integrated institutional research in cancer, and the advancement of broadly based but carefully coordinated research programs, are considered essential to the development of the critical mass of scientific effort on cancer requisite to effective progress in the field. The Sloan-Kettering Institute for Cancer Research is one of about a dozen American research institutions wholly devoted to the investigation of cancer. Such programs can best be reviewed and most intelligently supported as a whole. Consequently, the judgmental process involves different considerations from those surrounding the review and selection of individual research projects for support.

In the latter process, the determinations center around the characteristics of the specific project proposed and the individual investigator involved as viewed by his scientific peers in the discipline or specialty in which the work falls. It is important to understand that when such review groups or study sections evaluate research quality, they do so from the perspective of their own discipline orientation. From this point of view, study sections quite often disapprove or assign lesser priority ratings to projects because they consider them "routine" or "unimaginative" or as not contributing to fundamental advance in a particular field. These judgments of research proposals are usually made in comparison with other research projects in the same discipline and in the context of scientific trends in that field. The review groups do not make, nor are they expected to make, judgments about the importance or necessary relationship of the individual project to the broader research setting or program objectives of which it may be an integral part.

In the development of large and complex research programs involving many investigators working in an organized institutional setting toward a common goal, the focus of the judgmental process shifts to the whole: the stature and record of the institution, the scientific direction and leadership, the character of its scientific program, the internal and external arrangements for review and evaluation of its research activities, and the action needed to sustain and enhance the effectiveness and accomplishment of its research program.

These considerations underlie the development by the National Cancer Institute of the concept of single-instrument support and the sharing of an institution's total research costs.

The advantages of the single instrument to both grantor and grantee are its comparative simplicity and clarity in presenting the grantee's total program for review and evaluation. The grantor gains by obtaining a total picture of the grantee's scientific and administrative structure and operations, and by reduction in paper work and duplication of effort involved in reviewing the same structure in separate segments at various times (as is necessary when a large institution is supported by individual project grants). The grantee gains by the assurance, once the grant is awarded, of secure support for a substantial area of program, thus

enhancing ability to attract and retain the best-qualified investigators. Additional responsibility is placed upon the grantee's management for performance sufficiently effective and standards sufficiently high that the institution will continue to deserve Federal funds.

The use of this form of support will obviously be limited, but nonetheless will be cautiously extended to other institutions when considered appropriate. Only institutions that reflect the aggregation of the following unique set of specific characteristics will be considered suitable:

- devoted exclusively to a categorical and definable research objective,
- a comprehensive and diversified research program,
- a basically noninstructional environment permitting an array and proportion of research effort not usually found in the discipline-oriented departmental structure of the university,
- a tradition of effective scientific and administrative management and the means for achieving it.

The Sloan-Kettering Institute was considered to meet each of these characteristics. SKI has long had an effective central management which makes scientific and business decisions, determines the investment in various facets of cancer research, and fully controls its operations. This management is reinforced by outside advisers of scientific eminence and is given regular overall review by a board of trustees of responsible businessmen and scientists. SKI's system of thorough continuous review, both administrative and scientific, was a major factor in the NIH's selection of this institution for the first experiment in the application of the single instrument of support.

The nature and content of the agreement developed for the support of SKI programs, together with the scientific program of the Institute, were scrutinized by a panel of distinguished consultants and by the National Advisory Cancer Council, which recommended approval. Although the grant involves a five-year "moral commitment" of support in keeping with the usual NIH practice of providing reasonable assurances of stability for grant-supported work, the agreement requires NCI approval of all program changes as well as an annual comprehensive review of the scientific content of Sloan-Kettering programs by NCI selected consultants. The total funding level was set slightly below that provided to SKI under the then existing project-support arrangement.

In respect to the Committee's concern for the withdrawal of significant sums from the competitive research project system, it should be emphasized that funds for single-instrument support are in full competition with other support mechanisms at the Council level.

The application of this single-instrument plan to other institutions will depend on (1) the results, after a sufficient period of time for a fair assessment of this first experiment with Sloan-Kettering; (2) the suitability of other institutions for such support; and (3) the judgment of the eligible grantee institution.

There is no absolute way to assess the merits of this approach versus the old project approach. This, in the end, has to be the judgment of informed experts. NCI has established a functioning committee to study the problem. In addition, SKI is supplying necessary data so that when the relationship approaches the end of the committed period, a judgment can be made as to whether this method of support is suitable and what changes are needed, if any, or whether, if the single instrument proves unsuitable, this approach should be dropped. At present the grant has been in effect too short a time for evaluation. If it ultimately proves ineffective, NIH must develop another pattern of support in a continuing effort to arrive at the one which will engender and sustain the best environment and Federal-nonfederal relationship for solving the cancer problem and other comparably broad and complex problems in medicine.

Thus the Department is convinced that the measures taken by the National Cancer Institute to provide broad support for comprehensive research programs of institutions centered upon the cancer problem constitute a warranted, sound, and important step. The mechanism provides a necessary means to increase the concentration upon comprehensive, long-term research under arrangements which assure effective scientific direction, good management, and devotion to the public interest. Without question, such arrangements must be carefully developed and must provide for critical scientific and managerial review. Suitable arrangements have been made for that purpose, and their conduct and progress will be under departmental surveillance.

The legal basis for the Sloan-Kettering award is authority originally made available in the National Cancer Act of 1937 (27) and broadened to the entire Public Health Service under the PHS Act of 1944. (28) This provision of law authorizes the Surgeon General, when conducting or supporting research and investigations into disease and related health problems, to adopt upon the recommendation of the National Advisory Cancer Council or other appropriate Council "such additional means as he deems necessary to carry out the purposes of this section." (29)

This is a critically important element of the framework of law governing the basis of national action in matters relating to health. The Comptroller General has consistently held in opinions rendered upon this specific point of law that it gives clear evidence of the intent of Congress to provide broad authority for the Surgeon General to act upon recommendation of an Advisory Council in the manner he deems necessary to investigate a disease problem or undertake matters related thereto. (30) In these opinions the Comptroller General has emphasized

that "grants-in-aid under section 301 of the PHS Act are not limited to grants for research projects such as are specifically authorized by subsection 301(d), but that, in view of the authority vested in the Surgeon General under subsection 301(h) (now i) to adopt such additional means as he deems necessary or appropriate, grants may be made for other purposes determined by the Surgeon General to be necessary to carry out the purposes of section 301." (31)

To be able to act in exceptional circumstances, and to undertake special arrangements in furtherance of research, not only in cancer but in comparably urgent and difficult health problems, are viewed by the Department as essential provisions of law for the discharge of national responsibilities in the health area.

Thus the Department does not support the Committee's recommendation that Congress amend this provision of the Act with the intention of limiting the authority, now resident in the Secretary of HEW, (32) to undertake such necessary and appropriate action in respect to the conduct and support of research in matters related to health and disease.

Because of the breadth of this authority, however, the Department concurs in the view that it should be exercised only after careful consideration of the circumstances involved. Hence, the formal delegations of authority within the Department are being reviewed to assure that there are appropriate restraints on the use of this authority.

Quality of Research

The Committee, in the section of its report entitled Sharpening the Instruments of Support, states that NIH and PHS have never clearly defined the qualitative level expected of applicants seeking support for their research; that it is unclear whether the objective is to support high-quality research or extend support to all "competent" investigators; and that the available evidence indicates that research of less than good quality is being supported.

The principal evidence cited for this allegation is a table showing a distribution of approved grant applications by priority ratings for the years 1956-1966, which shows for 1966 a lower percentage in the 100-199 (highest priority class) than for 1956. The Committee concludes that "in the light of the continued lowering of research standards and the excessive diversion of scarce professional personnel from teaching and medical practice to federally supported research," it must answer in the negative the question "whether or not it is sound public policy and in the best interest of science that every project found technically sound and approvably by NIH's outside consultants receive support, regardless of its relative quality."

The Committee then puts forth Recommendation No. 9:

" . . . that the Surgeon General establish a high standard of quality as the basic qualification for research project support, and that he develop adequate procedures for the uniform maintenance of that high standard by NIH and other bureaus of the Public Health Service. The confinement of research grants to projects in the range of excellent to good should not be breached except in special circumstances where the reasons for supporting a lower quality project are fully documented in a written record."

At the outset of this discussion of the Committee's findings in respect to the quality of research being supported under NIH programs, the Department wished to emphasize that there has not been a "continued lowering of research standards" in the conduct of these programs, nor has "a much lower level of competence . . . replaced high quality as the standard for determining whether research is worthy of Federal support." The available evidence, to the extent that it can be considered to reflect qualitative trends, clearly does not support this statement.

In examining this matter the role and function of PHS and NIH in the conduct and support of research must be kept clearly in mind. PHS and NIH are health agencies concerned with the solution of health problems and with advancing the health status of the Nation. In discharge of this primary mission, the objective of the programs administered by NIH are--

- to achieve a greater understanding of the biological and behavioral phenomena underlying disease, disability, and health--through broad inquiry into life processes;
- to advance existing capability for the maintenance of health and for the diagnosis, treatment, and prevention of diseases--through expanded and enhanced scientific, academic, and technological efforts and resources; and
- to accelerate the effective flow of new knowledge and technological capability from the centers of academic medicine to the universe of health practice.

Thus NIH is not simply a science agency concerned with expanding the fund of man's knowledge and the advancement of science and scientific resources as such. In the conduct of its programs NIH is concerned not only with quality but with relevance; not only with current work but with the development and expansion of further capability, and consequently with the entire framework of resources, manpower, facilities, and institutional commitments which comprise the national system for the advancement of knowledge and technology for health purposes. Furthermore, NIH must provide support not only for the brilliant advances of scientific knowledge, but also for the important scientific effort required to elaborate and extend those advances in a manner meaningful to the problems of health and disease. Support must be provided not only for men who have achieved distinction but for the men of promise from which will emerge the scientists of distinction of tomorrow.

The support of investigator-initiated research projects through the Regular Research Grant programs of NIH is a major and long-standing component of NIH operations. What is expected of the individual investigator under this program of NIH is the sine qua non of science; to propose scientifically meaningful research of the best that he is capable. A scientist can do no less. The selection of such projects for the award of grants is through a process that assigns determinant roles to peer groups, notably study sections and advisory councils. This review system, which derives from the statutory requirement for affirmative advisory council recommendations prior to award, constitutes a truly unique achievement in meshing the considerations of public purpose with the criteria and values of science in the conduct of Federal programs. The process has been subjected to numerous critical examinations and broadly judged to be sound, effective, and conducive to the interests of both science and the public. (3,4,5,9,10,13)

Under this system, research grant support is awarded to those research proposals (1) judged by study sections as scientifically meaningful, important, and possessing a high probability of yielding useful results, and (2) judged by Advisory Councils as having significant relevance to the program objectives of NIH and thus recommended as worthy of public support. It should be pointed out that only those applications which the study sections consider worthy of support are assigned a priority score and recommended to the councils.

The standards of this process are rigorous. The result: As the number and dollar value of research grant applications has increased, the proportion of applications surviving this review has fallen. In recent years almost half of all the new and 40 percent of the competing research grant applications received by NIH have failed to pass the basic qualitative threshold and have been disapproved. The following chart shows this trend graphically.

The priority scores utilized in the review process are assigned to applications only after they have been approved by a study section. Thus, the scientific merit of a project and its eligibility for NIH support have already been established. The purpose of the priority score is less to quantify quality in an absolute sense than to provide a means of gaining a collective opinion of the reviewers for ranking the applications recommended for payment. This is not to suggest that priority rating is unrelated to scientific merit, but other subjective variables are reflected in these numerical indices. To illustrate: Given two project proposals of corresponding scientific merit, one an epidemiologic approach, another a laboratory technique, one reviewer might assign higher priority to the former as a consequence of his conviction that the "state of the art" in that science-discipline calls for more emphasis on epidemiologic studies. Thus, priorities reflect scientific choice as well as scientific merit.

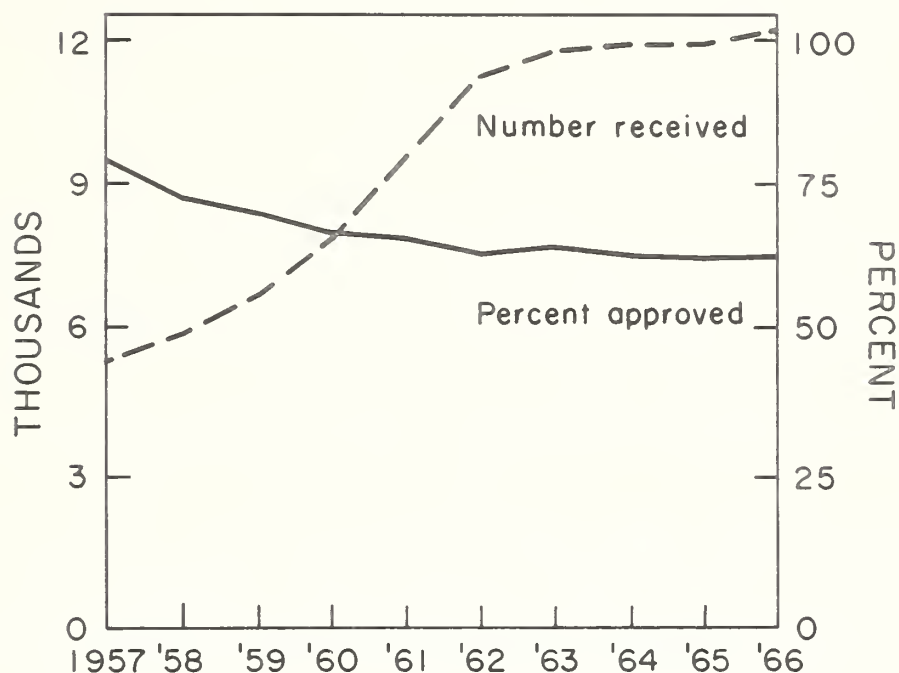
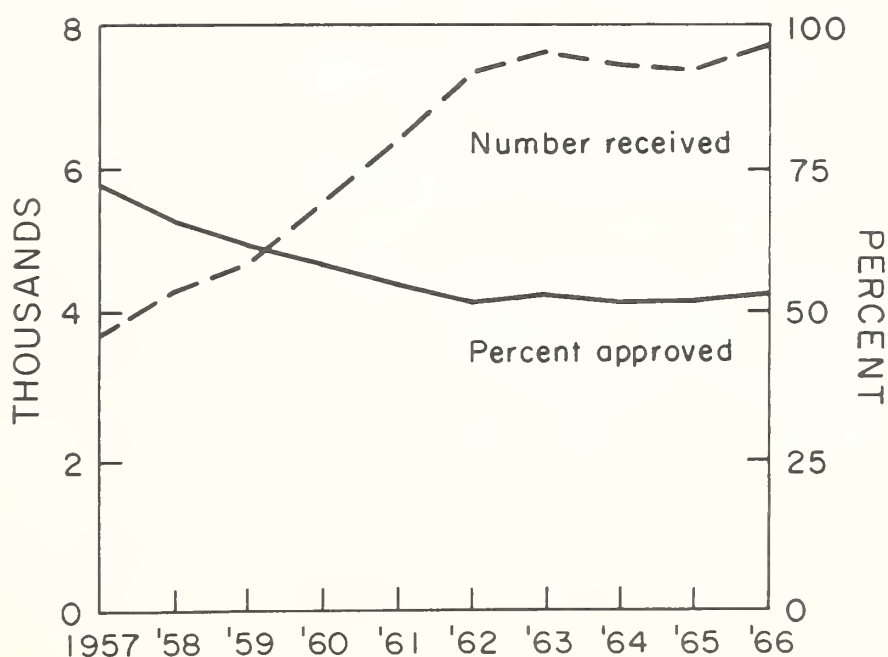
There is no valid basis for equating the 100-500 priority scores with such value words as "excellence," "very good," "good," "fair," and "poor." As nearly half of all new applications have already been discarded, even the applications receiving the lesser priority scores have been judged as meritorious and thus worthy of public support.

Another difficulty with the Committee's analysis is the fact that its assessment of the trend in priority scores is based on a comparison of 1956 and 1966 without recognition of the fundamental differences in the scope and magnitude of NIH programs wrought by the Congress in the intervening decade.

In 1956 the NIH appropriation for project-grant support was \$40 million, which represented 13 percent of the estimated total national expenditure on medical research (\$312 million) and involved the support of only 2500 projects. The national need was great and the research capacity of the Nation substantial; national programs were severely limited (a heritage of the Korean war); and only established investigators, research programs, and institutions were being supported. The skewing of priority ratings to the upper end of the scale during the period when these conditions were in substantial dominance was inevitable.

Ten years later the universe of medical research was transformed. National expenditures in this area totaled over \$2.0 billion, of which the Federal share was \$1.3 billion and the NIH figure was \$791 million, the predominant share of which was expended in support of almost 16,000

TREND OF APPROVAL RATES

FIG. 1—COMPETING RESEARCH
GRANT APPLICATIONSFIG. 2—NEW RESEARCH
GRANT APPLICATIONS

research projects. These are the dimensions of a national medical research effort which is not only of a wholly different order of magnitude, but is beyond equating in respect to the scope and depth of the science involved or the investigators and institutions engaged, and to the extent to which the national interests are being served. To ignore these massive changes and to assume that the priority rating pattern of 1956 is a valid base of comparison with the pattern of 1966 hardly seems reasonable.

Furthermore, it would be difficult, indeed, to demonstrate any meaningful change in the priority character of research grant applications after the initial period of rapid program growth. Thus, since 1960 the distribution of priority scores--as shown by the table printed in the Committee's report--has remained virtually constant with:

- about 24 percent in the 100-199 group,
- about 48 percent in the 200-299 group,
- about 25 percent in the 300-399 group, and
- only 3 or 4 percent in the lowest priority category of 400-500.

In 1966 and 1967 the proportion in the highest priority group has shown a distinct increase, to 26 percent and 30 percent respectively.

The problem of the prospective assessment, maintenance, and retrospective evaluation of the quality of research activity is admittedly a most complex, difficult, and uncertain matter. The Wooldridge Committee's assessment of NIH is perhaps the most carefully developed and executed attempt to submit a national research program to qualitative judgment.⁽¹⁰⁾ The statistical framework for assessment was designed by the country's leading statisticians, and the work of assessment was carried out by expert panels in all the major scientific fields.

A more complete statement of the Wooldridge Committee's findings than that provided by the Report in question is needed to give the full force and deliberateness of the judgment reached:

"One of the principal purposes of this study was to evaluate the quality of the research currently supported by the National Institutes of Health. Because of the competence and distinction of the consultants who performed the survey for us, as well as the extensiveness of the survey itself, we have considerable confidence in the validity of our conclusions regarding the general quality of the NIH activities.

". . . Out of the 240 'traditional' extramural research grants investigated, the panel teams expressed serious reservations about 9 projects and adjudged an additional 7 to be unworthy

of support. In scientific research, such a ratio of ill-advised projects, when judged after the fact, is impressively low. Much more frequently, NIH-supported work was found to set the national or international standard of excellence in its field.

" . . . The opinion of the Committee, based on the extensive investigations of its consultants, is that the large majority of the intramural and extramural research supported by NIH is of high quality. We strongly approve the peer evaluation method of selecting recipients of extramural grants

"Despite the tenfold increase in NIH support of research during the last eight years, there is no evidence of over-all degradation in quality of the work supported. On the contrary, there is good evidence that the average quality is steadily improving. This appears to be a consequence of a rate of increase in the production of competent biological research scientists matching the over-all rate of increase in research support."

The Committee report notes that the careful attempt of the Wooldridge Committee to assess the quality of NIH projects found that less than 7 percent of the regular research project grants could be considered in retrospect to have been ill-advised. As the Wooldridge Committee report points out, this ratio, 7 out of 100, probably represents the limits of human capability in making prospective judgments of the probable quality of research yet to be undertaken.

The Commission on Medical Research of the American Medical Association also considered the quality of research being supported through NIH programs and the process of reviews. Its conclusion was as follows:

"The study section arrangement organized by the NIH for review of proposed project grants through panels of outside academic experts (or peer groups) has been successful in identifying and supporting research of quality"(13)

As a consequence of its examination of all the considerations surrounding the Committee's comments on the quality of research being supported through NIH programs, the Department concludes, as noted at the outset of this discussion, that there has not been a "continued lowering of research standards" in the conduct of these programs nor has "a much lower level of competence . . . replaced high quality as the standard for determining whether research is worthy of Federal Support." The available evidence, to the extent that it can be considered to reflect qualitative trends, suggests quite the opposite trends.

Thus, in respect to the Committee recommendation that a high standard of quality be the basic qualification for research project support and that adequate procedures be developed to maintain that standard, the Department believes that the existing arrangements have given and will continue to give firm assurance that only projects worthy of public support for the accomplishment of the statutorily established objectives of NIH programs will be awarded grants.

In respect to that part of the recommendation relating to the circumstances under which projects fall in the lower priority ratings, present procedures require that any application falling in the lowest 10 percent of the priorities assigned by any Study Section be subjected to special review by staff and the relevant Advisory Council before an award is made. This process assures that applications receiving the lowest decile of priority ratings are only approved if they are thus deliberately selected for their importance to some aspect of the relevant Institute's program. This procedure has been in effect since June 1959 in response to criteria set by President Eisenhower.

Concentration of Grants

The Committee's Report notes the concentration of NIH research and training grants in a limited number of institutions and expresses concern about the implications for the welfare of institutions not participating so extensively and for general distribution of national research resources. On the basis of its examination of this matter, the Committee expresses its view that the responsibility for Federal programs intended to strengthen institutions of higher education should not be diffused among agencies. The Committee therefore makes Recommendation No. 10:

". . . that the Public Health Service's responsibility for programs designed to develop or improve the capability and resources of educational institutions be limited to medical and other health professional schools. The general research support program is not included in this category since the Congress authorized these grants, permitting broad discretionary spending, specifically to supplement project grants. The committee recommends that the responsibility for grants intended to strengthen educational institutions other than health professional schools be confined to the National Science Foundation and/or the Office of Education--the two Federal agencies broadly responsible for strengthening basic science and education."

The present pattern of Federal support for research and graduate education is a consequence of the delays, uncertainties, and controversy in which Federal policies and programs for the support of science and education have evolved. Failure to reach an early national consensus on the concept and role of the National Science Foundation in the immediate postwar years contributed substantially to embedding the major support for academic science and graduate science education in the programs of mission-oriented agencies such as NIH, ONR, and AEC. Despite the final enactment of the National Science Foundation Act and the eventual broadening of the role of the Office of Education, the preponderant portion of the Federal funds received by academic institutions comes through the programs of mission agencies. Less than 20 percent of the total is provided by NSF and OE.

The primary responsibility of mission-oriented agencies is for the accomplishment of their statutory objectives, in which support of graduate research and education is approached primarily as a means and not as a principal end. Thus the pattern of institutional distribution of NIH support is the consequence of the vigorous pursuit of statutorily established missions under criteria of scientific merit and relevance. The suggestion

that "favoritism" in the review process and skill in "grantsmanship" are significant factors in the distribution pattern of NIH support is a superficial observation unsupported by fact.

To the maximum extent compatible with the achievement of the overall objectives and the limitations of law, effort has also been extended to expanding the national capability in the health sciences. That there is a concentration of NIH support in institutions with broad research programs of excellence is therefore necessary and, in the context of mission responsibility, a desirable circumstance. If, indeed, the distribution of NIH support reflected a substantially different pattern, according equal treatment institutionally and geographically, there would be a basis to question whether its statutory responsibilities were being properly discharged, or whether other purposes than those for which its funds had been appropriated were being served. It is also appropriate to note that the tendency of NIH awards to discriminate in favor of institutions with demonstrated capability reflects the same concern for quality that the Committee expressed in an earlier section of their report.

The basis of this concentration of NIH support does not deny the importance of attention being paid to broadening the institutional base for the health sciences. In this respect NIH programs have been administered in a manner which steadily and progressively has increased the total number of institutions nationally participating in these programs. At the present time, almost 500 different educational institutions participate in NIH research and training programs. This is almost twice the number of such institutions that were participating in the program in 1959. Enlarging the number of institutions of excellence in the biomedical sciences of the Nation has been an objective to which NIH has consistently directed its effort and which constitutes the basis of the conduct of its Health Sciences Advance Award program.

A policy that would limit NIH efforts to improve the health-related research capability and resources of educational institutions to medical and health professional schools would not be compatible with the realities of existing Federal-university relationships, as noted above, nor with the scope of science upon which the advancement of health capability depends.

The last several decades have seen the evolution--principally in non-health professional components of graduate schools--of hybrid scientific disciplines such as biochemistry, biophysics, and biomathematics into strong and viable areas of scholarly endeavor. These new sciences represent points of contact and areas of interdigitation between the sciences of chemistry, physics, and mathematics and that of biology. New knowledge developed in these hybrids, particularly in specific subdisciplines, has proved to be enormously significant for health. There is every reason to believe that fundamental insights into health problems will continue to flow from these sources.

On another front, the engineering sciences have as yet interacted only marginally with biological and medical sciences, and formidable barriers between them remain to be breached. Yet many thoughtful scientists and scientific administrators believe that interpretation of these sciences holds enormous promise for the advancement of health knowledge. Thus the Nation's schools of engineering are considered as one of the presently most fertile grounds for the development of institutional capability in the biomedical sciences.

In yet another area--the behavioral sciences--access to the non-health professional components of graduate schools is an indispensable requirement if further advancement is to be made in many critical health problem areas.

The Department believes that there are important and noncompetitive developmental roles to be played by NIH, NSF, and OE in the non-health professional components of this Nation's graduate schools in the present context of national policies and arrangements for support of university functions. OE's mission is the broadest and most general--to support the basic process of graduate education and the basic educational enterprise. NSF has primary responsibility for education and basic research in the sciences generally, including mathematics and engineering. And NIH must focus on research and research training in the sciences related or oriented to health.

Thus, in respect to the Committee's recommendation that NIH's programs directed towards the improvement of the capability and resources of educational institutions in the biomedical area be confined to medical and other health professional schools, this Department believes that such modification would impair the achievement of national objectives in the area of health and medical research in the present context of Federal relationships to educational institutions.

Rather than expend effort on this limited modification of Federal-university support arrangements, the Department is of the opinion that the public interest could probably be better served by directing attention to the problems and needs of the basic academic functions as such and the development of national programs that will provide for the long-range development of institutions and permit Federal support across the full scope of graduate education and the expansion of intellectual effort in the social sciences, arts, and humanities, as well as the natural sciences. Further considerations in respect to this matter are discussed in the departmental response to Recommendation No. 14.

Aiding Weaker Institutions

The Committee in its report expresses concern over Federal policies that discriminate against schools that do not already have extensive research programs, and views the present General Research Support and Biomedical Science Support programs of NIH as contributing to that discrimination. To provide for more equitable treatment of the smaller and less wealthy institutions, the Committee, in Recommendation No. 11, proposes the following changes in PHS policies:

"(1) Qualification for a GRS grant should be based on a school's receiving \$100,000 or more annually in research project grants from all units of the Public Health Service combined, rather than exclusively from NIH. Moreover, HEW should consider broadening the GRS program, with appropriate legislative authority, to include health-related research grants made by other units of the Department in such programs as vocational rehabilitation and maternal and child health. Eventually, a single general research support grant for each eligible institution, administered on a Government-wide basis, would be most efficient and desirable.

"(2) The amount of each GRS grant should be determined solely on the basis of the institution's research expenditures from Federal sources. The committee does not believe the premium given for non-Federal research funds under the existing formula operates as a meaningful incentive for attracting private funds. Rather, this premium discriminates against poorer institutions, favors research organizations over institutions of higher education, and, as demonstrated in chapter IV, has been difficult to administer and wasteful of Federal research money.

"(3) The same GRS eligibility requirements should be applied to health professional schools as to other institutions. To the extent that health professional schools require assistance in developing a research capability, this should be accomplished by a separate program of technical and financial assistance tailored for the purpose.

"(4) The separate biomedical sciences support grant should be discontinued, and the GRS grant awarded to graduate schools on the same terms as to professional schools, hospitals, and research institutions.

"(5) Until such time as a single general research support program may be established on a Government-wide basis, the NIH program and NSF's institutional grants program should be closely coordinated to avoid duplication. Some institutions presently receive general research support from both NIH and NSF computed on the basis of the same research projects; this occurs because NSF bases the amount of its award exclusively on the research (as well as some research training) grants it makes, while NIH includes these same NSF research grants in the computation for GRS awards."

As noted in the prior section of this response dealing with the General Research Support program, this program was designed to provide support for the health research and research training programs of institutions and thus to complement project support for individuals within those institutions. Its major intents were to provide funds to redress imbalances and inflexibilities created by categorically oriented research-project grants; to foster autonomous institutional growth in the health sciences area through the development of research and research training programs in accordance with self-defined institutional aspiration; and to create and operate the central resources and facilities used in common by many biomedical scientists within the institution.

In evaluating the meaning of "equitable" utilized by the Committee, one should not lose sight of the fact that intrinsically the GRS program is discriminatory. It was intended, within limits, to provide support in proportion to the imbalance or straining of institutional programs by categorically oriented research project grants from NIH. Institutions were not to receive awards unless a reasonable basis was evident to conclude that such distortion operated. Hence, a threshold, defined in terms of dollar amount of NIH support, became a necessary (but not sufficient) requirement to be met in establishing institutional eligibility.

If the Committee report's allusion to "smaller and less wealthy institutions" is to those without significant amounts of NIH grant support, then it should be recognized that their concern relates to institutions in which the conditions that the GRS program sought to redress do not obtain. The GRS program was not designed to assist small schools as such or those whose financial strength, in absolute terms, was minimal. This is not to deny that the development of these institutions is in the public interest or that the Federal agencies should play a role in the process. But the NIH has, under its present authorities, little justification for providing this type of assistance to institutions whose current research activities are very modest. And, surely, an institution which has been unable to win more than \$100,000 in awards--on the average, three grants--in national competition for more than \$600 million in NIH research grant appropriations, must be regarded as a biomedical research program of extremely modest proportions.

The institution-building activities of mission-oriented research and development agencies, especially when undertaken under statutory authorities for research, should be predicated upon significant and demonstrated research capability in the relevant sciences. The Department concurs in the NIH view that its responsibility for smaller and less wealthy institutions under the GRS program begins only after the institution has reached a degree of competence measurable--albeit somewhat arbitrarily--by a level of NIH awards of \$100,000 and by the assessment of advisors that the research program of the institution is broad, diverse, and complex. For institutions that have not yet reached this stage, the General Research Support program is not an appropriate mechanism of support.

The intent of these remarks is to introduce a note of caution into the formulation of the concept of "equitable treatment" when applied to the "smaller and less wealthy institutions" under the GRS program.

Thus, in respect to the general purpose of Recommendation No. 11, the Department shares the concern expressed in the Committee report for institutions which are small, or modestly endowed, or outside geographic areas of high-population density. With the Committee, the Department believes it to be in the national interest to upgrade the research capability as well as the general excellence of all classes of institutions of higher learning. However, the Department is persuaded that the fundamental considerations involved in seeking this objective are so different from those toward which the General Research and Biomedical Support programs are directed that, as noted above, a broader national program should be devised for this purpose.

In respect to the specific components of Recommendation No. 11, many of the changes proposed are ones that have been under consideration within the Department. If the Report of the National Academy of Sciences-National Research Council evaluative study of the General Research Support program had not cautioned against such action before at least 1967, and were it not evident that some of these actions, if taken precipitously, would have serious adverse effects on specific institutions, several of these recommendations would have been put in force some time ago.

The Department concurs in principle with the Recommendation 11(1) that the eligibility base for general research support be broadened beyond the present NIH base. Plans for effecting this will be developed within the coming year. With regard, however, to expanding this program to make possible a DHEW-wide and, eventually, a Government-wide general research support program, the Department has misgivings. These derive from the conviction that the changes would inevitably reduce the effectiveness of these funds in achieving the statutory missions of the separate Federal agencies which support research and development efforts in their respective fields of interest in eligible institutions.

The Department concurs in principle with Recommendation No. 11 (2), the effect of which is to terminate automatic eligibility for those classes of health professional schools initially declared eligible when the program began in 1962. However, it reserves the right to put this change into effect in such a way as to minimize dislocation and adverse effects in grantee institutions, and further hopes that new authorities and funds will become available to develop research capability and otherwise strengthen some of the previously eligible institutions which need and have no other source of such support. Particular consideration will be given to the problems of these institutions in the legislative submissions that relate to the extension of the Health Professions Educational Assistance Act.

The Department wishes to study more carefully Recommendation No. 11 (3), to discontinue the Biomedical Sciences Support Grant program. The view at NIH is that there should be as many fund-allocation formulas as there are homogeneous classes of institutions in terms of institutional importance as a performer of health-related research. It may turn out that no distinctions sufficiently important to warrant separate categorization should be made, in which case the recommendation will be accepted. Alternatively, two or even more programs may appear most appropriate.

The Department concurs in Recommendation No. 11 (4) that there be close coordination between NIH and NSF in the evolution of their respective programs of the type that NIH calls general research support. At the moment they are the only sources of Federal support for such programs. It should be noted that coordination has been practiced in the past, even though differences of opinion--which the NIH believes to be entirely appropriate--on some problems continue to exist.

As noted in response to Part 1 of Recommendation No. 3, this Department has directed PHS and NIH to submit to the Secretary a plan for the modification of the formula utilized for calculating the awards under the General Research Support Grant program which provides for the elimination of the premium factor for nonfederal research expenditures, as well as other changes considered desirable, to be effective with the GRS awards made for fiscal year 1969.

This plan will also take into account the foregoing recommendations of the Committee.

Training Grant Programs

The Committee notes that certain educational institutions which receive very little PHS research and training support award a significant number of doctoral degrees in the health-related sciences. Thus, Recommendation No. 12:

" . . . that the Secretary of HEW review the numerous NIH and other PHS training grant programs to determine if they are effectively organized to serve national manpower needs and objectives. This review should be concerned particularly with ascertaining if the institutions which receive large amounts of training funds are making a proportionate contribution to the nation's manpower supply. Conversely, the Secretary should determine if training grant policies discriminate against schools which award graduate degrees in the biomedical sciences but receive little or no PHS training support."

NIH training programs provide support for both predoctoral and postdoctoral training in the biomedical sciences. Approximately 65 percent of the support covers predoctoral training, with heavy emphasis upon the basic medical sciences, and about 35 percent covers postdoctoral training. Because of the inclusion of this significant postdoctoral training component, there is not necessarily a 1-1 correspondence between NIH training support and doctoral output in the basic medical sciences.

In 1965, the most recent year for which data are available from the Office of Education on Ph.D. output, graduate students receiving stipend support through NIH training grants accounted for nearly 42 percent of all Ph.D.'s awarded in the basic biomedical sciences, 48 percent of Ph.D.'s awarded in nutrition, and 33 percent of Ph.D.'s awarded in genetics. It should be emphasized, however, that these data understate the contribution of NIH training programs to Ph.D. output. Ph.D.'s are also awarded to individuals receiving support through NIH research fellowship programs, to those who have had NIH support in prior years but not necessarily the year in which they secured their degree, and to individuals employed as research assistants on research grants, frequently utilizing their research for dissertation purposes.

Of the top 35 institutions receiving PHS training grant funds in fiscal 1966, 23 also rank in the top 35 with respect to Ph.D. output in the biosciences. The twelve institutions that do not rank in the top 35--NYU, Pittsburgh, Washington U. (St. Louis), Western Reserve, Yeshiva, Boston U., University of Colorado, Emory, University of Southern California,

Oregon, Baylor, the University of Iowa--all have medical schools with strong postdoctoral training programs. In 1964-65, 6 of these schools reported Ph.D. output in the biosciences, ranging from 11 to 18 Ph.D.'s; and the other six schools each reported less than 11 Ph.D.'s in the biosciences, but with clear evidence of substantial increases in graduate enrollment in the biosciences which are likely to appear as increased Ph.D. output in subsequent years.

This information is indicative of the close relationship between the NIH training programs and the national capability for the production of trained scientific manpower in the health-related sciences. NIH training grant support is provided not only with respect to the intrinsic scientific quality of institutional programs, but also in terms of the relevance of the proposed training to the authorized mission of the awarding NIH Institute. It is not possible, therefore, for NIH training grant support to be provided to every environment simply because it awards advanced degrees in the biological sciences. Rather, training grant awards must continue to be made selectively on the basis of the twin criteria of scientific excellence and NIH mission relevance.

Nonetheless, the Department concurs with the Committee's view of the importance of assessing the effectiveness of NIH training programs in meeting urgent national needs for biomedical research manpower. Thus, in respect to Recommendation No. 12, the Department is directing the National Institutes of Health to extend its already broad and thorough review of the biomedical research manpower area now under way. The findings and conclusions of these studies are expected to be available during the forthcoming year. A subcommittee on manpower of the Advisory Committee to the Director of NIH has recently been established to provide guidance in the review of NIH training programs. It is anticipated that the advice and recommendations emanating from this group will also be of significant value in determining the appropriate NIH training role and responsibilities in the years ahead.

Technical Assistance to Institutions

The Committee comments on the desirability of helping weaker institutions upgrade themselves and the importance of such institutions' learning how to achieve quality in their education and research programs. In this respect the Committee proposes Recommendation No. 13:

" . . . that the President designate one or more Federal agencies to provide technical assistance, upon request, to help institutions plan for the improvement of their science education and research programs. It would be logical for the Public Health Service to be concerned with the health professional schools; other groups of institutions in which the biomedical sciences are taught might be made the responsibility of the National Science Foundation and/or the Office of Education."

While deferring to primary concern of the Executive Office of the President in respect to this matter, it should be noted that the Department has actively supported and participated in interagency efforts to this end and will continue to do so. Among the several actions taken within the Executive Branch in respect to this matter, the following seem pertinent to the objective of this recommendation:

1. The establishment of the Federal Interagency Committee on Education (FICE) in October 1964, by Executive Order 11185. This provided an essential element: the formal mechanism through which interagency coordination and cooperation toward common education goals could be made effective.
2. The President, on September 14, 1965, issued a memorandum on "Strengthening Academic Capability for Science," focused on the need to develop centers of excellence in the academic sciences in all parts of the Nation. This directed the heads of all Federal agencies with substantial R&D programs "to develop academic capabilities for research and scientific education as a part of their research missions." This same memorandum assigned the following specific responsibilities:
 - a. "The National Science Foundation continues to have responsibility for augmenting the research capabilities of academic institutions in all fields of science through the support of basic research and research facilities and through measures for improving the quality of education in the sciences."

- b. "The Department of Health, Education, and Welfare will contribute to the overall development of colleges and universities and to the development of health professional schools, particularly through programs of the Office of Education and the Public Health Service."
 - c. "The President's Science Advisor is to help the Federal Council of Science and Technology to follow agency responses to this policy and to report monthly progress."
3. As a followup to the President's directive, a Federal Interagency Committee on Academic Science and Engineering (CASE) was set up under the Federal Council of Science and Technology. This group has met frequently, directing its activities to clarification of policy issues and the relationships of ongoing programs, to develop a national framework of institutions competent in the academic science areas.

Thus, in respect to Recommendation No. 13, this Department feels that sufficient preliminary steps have already been taken by the Executive Branch so that it should be possible, within a reasonable period of time, to designate specific "cognizant agencies" for providing technical assistance in the development of academic science capabilities in respect to particular categories of institutions or areas of research. However, it is felt that it would be premature, pending the further development of these concepts, to make the division of responsibilities for the biomedical sciences suggested by the Committee.

Improving the Academic Quality of Graduate Institutions

The Committee emphasizes the importance of strong graduate programs of excellence in relationship to national needs for trained manpower, and urges study of doctoral degree standards as an essential element of efforts to extend national programs in this area. In this respect the Committee also notes the paucity and diffuseness of Federal activity directed toward improving the academic quality of weak graduate institutions and recommends:

"Recommendation No. 14.--. . . that the President give early attention to the problem of improving the academic quality of weaker graduate institutions and that a unified and coordinated Federal assistance program be developed for dealing with this matter. The committee believes the present piecemeal and uncoordinated approaches of Federal agencies to institutional improvement are competitive, wasteful, and frequently not directed to the heart of the problem."

Again the Department acknowledges the principal concern of the Executive Office of the President with this recommendation, and thus comments only from its more limited purview.

Graduate education is the culmination of the formal process of equipping individuals with the requisite scholarly capability for independent teaching, research, and technical endeavor at the frontier of expanding knowledge and technological innovation. As a consequence of the evolution of this academic function over the past 50 years, the graduate schools of the United States now encompass a predominant portion of the intellectual force of the Nation. The Department is convinced that only through the careful cultivation of this resource can the Nation be assured of continuing capability to advance knowledge, to extend the base for technological progress, to influence the social, cultural, and economic quality of national life, and to exert intelligent and effective leadership in world affairs. Gaining a national consensus on this fundamental circumstance constitutes the major challenge to Legislative and Executive efforts to bring about a more rational relationship between the Federal Government and graduate education.

Unfortunately, the development of national policy and programs in support of higher education, academic institutions, and the graduate-research and professional-education functions of universities has unquestionably been piecemeal, disjointed, and as a consequence seemingly uncoordinated. This pattern is directly reflective of the controversy, conflict, and graduality that has surrounded the postwar evolution of a broadening consensus on the role of the Federal Government in respect to education and educational institutions.

The Federal function in research was quickly clarified and established as a consequence of the broad use of university science in the solution of war-related problems and the convincing evidence of the relationship of science and technology to national prowess. The Federal function in education has been and continues to be confronted with the fundamental issues surrounding the Federal-State relationship, the fear of Federal control of education, the church-state question, and the public versus private division of responsibilities. Thus the accretions of Federal activity in this area as authorized by the Congress have lagged far behind the Federal science role--have been segmental and almost random in coming into being and predominantly subordinate to other Federal purposes such as health, defense, and space. In large part these conditions still prevail.

There has been substantial effort on the part of the Executive Branch to compensate for and ameliorate the disjunctive effects of this historical development. As noted in the above section of this comment, the creation of the Federal Interagency Committee on Education, the formation of the Committee on Academic Science and Engineering, and the Presidential Memorandum of September 13, 1965, on strengthening academic capability for science throughout the country have all been directed toward this objective.

Fortunately, there appear to be encouraging indications of an emerging national recognition of the importance of cultivating the full scope of the intellectual resources of the Nation and the need to direct attention to the problems and requirements of academic institutions and their basic functions as such in a context distinct from their use in mission programs.

Legislation has been introduced in the last two Congresses seeking to establish a broader basis for Federal support of higher education--for example, H.R. 875. (33) The Secretary of HEW has constituted a high-level advisory committee on Federal-university relationships to contribute to the further evolution of policies and programs in this area. Under the direction of the Assistant Secretary for Health and Scientific Affairs, a broad review of programs in support of medical education is now under way, in search of more effective ways to relate national purpose in this area and the realities of institutional and educational needs. The conclusions reached in these examinations will be reflected in future departmental legislative proposals.

Thus, in respect to Recommendation No. 14, the Department shares the Committee's concern with the problem of improving the academic quality of weaker graduate institutions. The Department emphasizes, however, that the existing circumstances are not solely the consequences of the diffusion of Executive responsibility in this matter, but are basically reflective of the yet ambivalent and indecisive state of the national mind in respect to the manner in which national action in this area will be taken and the policies which should govern. Nonetheless, a considerable effort is under way within the Executive Branch to improve existing conditions and to further the resolution of national policy in this area.

Central Management of Grants

The Committee report reiterates the criticisms set forth in its earlier reports of the PHS framework for grants management--the degree of decentralization in PHS program administration and the tendency to place broad dependence upon the integrity and sense of responsibility of the institution receiving grant funds. Concern is expressed about the adequacy of organizational and staffing arrangements to ensure strong management of grant activities, and Recommendation No. 15 advocates--

" . . . that the Surgeon General (1) establish in PHS, and in each of the bureaus which administer grant programs, a single grants management office to provide uniform interpretations of policies and procedures, and (2) provide adequate staffing for PHS's Division of Grants and Contracts to enable this unit, on a current basis, to maintain surveillance over and liaison with the several bureau grants management offices to assure that policies are being properly and uniformly implemented."

In the initial section of Part II of this commentary, there is a review of the major efforts within NIH, PHS, and at the departmental level to advance the status and capability of the grants management function. The Department believes that substantial progress has been made in this area and that the framework is considerably stronger today than in the past.* The Department would also re-emphasize its previous statement that there is no disagreement in respect to the responsibility that bears upon the Department and its constituents for sound management of grant programs.

Without question, an increase in competent grant management staff and further progress in the coordination of the necessarily diverse activities is required. Thus, in respect to Recommendation No. 15, the Department is in full accord with the objectives sought. The planned reorganization of the health functions of the Department now under study will provide both the opportunity and the means to focus and strengthen further the grant management activities of each of the constituent agencies.

* See footnote, page 11 .

Advisory Committees

The Committee expresses concern about the tendency of the PHS to appoint a small group of individuals to multiple terms on Advisory Councils and other major advisory bodies, and the consequent appearance of favoritism in the process of selection. The Committee also reiterates its observation made in a previous report that a relatively small number of institutions which receive the bulk of NIH grant funds also furnish a majority of the consultants who serve in study sections. In respect to these matters the Committee proposes--

Recommendation No. 16:

" . . . that appointments to advisory councils be limited to one 4-year term, with members ineligible for reappointment, or appointment to other advisory councils, for a period of four years following the completion of their terms.

" . . . that consideration be given in the selection of advisory committees to obtaining a balanced representation of geographic regions and educational institutions. To the extent possible, consultants should be drawn from among qualified scientists who are not themselves recipients of PHS grants."

The National Advisory Councils are unusual, if not unique, in that they are not only established by law but have the statutory authority to make recommendations prerequisite to the award of a grant by the Surgeon General. These Councils provide the basic mechanism for broad public participation in the programs of NIH. This unusual framework for joining nonfederal advisers in the direct conduct of Federal programs has been remarkably productive and has achieved complete acceptance by the scientific community. Indeed, much of the rate of growth, scientific distinction, and public appeal of NIH programs is directly attributable to this engagement of both lay concern and technical competence in program affairs.

From the very beginning, when the first Advisory Council was set up under the National Cancer Act in 1937, appointments of professional advisers have been made on the basis of outstanding competence and stature among their peers. Lay members have been selected from among those who have demonstrated an interest in health or science and have enjoyed outstanding reputations in the field of public policy, education, or administration.

As a result of their expertise, Council members are frequently either recipients of grants or members of groups which depend heavily upon NIH for financial support. Consequently, the possibility of self-

interest or position affecting the views and actions of such individuals is present. NIH has imposed procedural safeguards on the advisory system to avoid the occasion of conflict of interest. In the ultimate analysis, however, the open nature of the NIH support system remains the most effective defense against favoritism, deals, and cliques, whether within the administrative groups or among the advisers.

Eligibility for reappointment, which is the subject of the Committee's recommendation for change, is covered by statute: reappointment of a member to the same Council is prohibited for one year following completion of a term of service.

The needs growing out of the evolving role of Councils, together with the enlarged number now involved in NIH programs, have already caused some difficulty in selection of candidates possessing the requisite stature, experience with problems of science policy, and motivation to meet the necessary demands in time and effort. This situation could be exacerbated by further restrictions on utilization of former members.

Thus, in respect to Part I of Recommendation No. 16, the Department recognizes the need for rotation of membership on National Advisory Councils as the best means for insuring that interplay of fresh and disparate viewpoints which will result in benefit, not only to NIH programs, but also to the national understanding and the exercise of national responsibility. A tightening of requirements for reappointment would be consistent with current committee management practices at NIH, which are now based on a limitation prescribed by law. At the same time, such modifications should be kept in balance: undue restrictions upon membership could result in denying access to the experience of advisers familiar with the diversity of NIH missions, with the operation of this complex system, and with the officials whom they are advising. Consequently, the selection and appointment procedures for National Advisory Council members are being revised to provide for special review of all recommendations for reappointment to assure that such reappointments are made only when there is clear evidence that the national interest is served thereby.

The selection and appointment of members of technical advisory committees present a different set of considerations. The maintenance or enhancement of ability to judge the scientific quality of proposals is paramount. Candidates for appointment are therefore selected primarily on the basis of outstanding qualifications as investigators in clinical or laboratory research. Because this review system is designed to assure the maintenance of scientific merit in the projects supported, it thus demands that its membership be selected on the basis of competence.

While giving overriding priority to competence as the dominant criterion in the selection process, the Public Health Service has also sought to achieve broad geographic and institutional representation in committee composition and to follow guidelines designed to broaden the representation of professional groups. Included in these guidelines,

for example, is a prohibition against an individual's serving concurrently on two application review committees, as well as a required lapse of one year before a member can be reappointed to the same committee. Appointment to the same committee of two individuals from the same institution is proscribed, while reappointment of reviewers who have already had long periods of previous service on advisory committees is explicitly discouraged.

It is a fact that many technical advisers to NIH are themselves recipients of grants. This is the inescapable consequence of the growth of the Federal support for biomedical research. The breadth and coverage of the thousands of active PHS grants encompass every relevant field of study in the spectrum of biomedical investigation. It is unlikely that any significant number of highly qualified biomedical scientists are not receiving some form of support through PHS programs.

PHS has taken care to ensure that there is no possibility of a conflict of interest when applications from its technical advisors are being reviewed. Accordingly, procedures have been developed that provide for review of a consultant's application by a group other than the one to which he has been appointed.

Thus, in respect to Part II of Recommendation No. 16, the Department must emphasize that the first requirement for selection of technical advisors is excellence in a specific field of research. Since excellence in science and medical research is not equivalently distributed in all States and all institutions, a proportionate representation in the distribution of PHS technical advisors by State and institutions cannot be expected. Inevitably the distribution of Federal support in mission programs follows the distribution of competence, which in turn forms the universe from which technical advisors must be selected. There appears to be no reasonable escape from this dilemma. To the maximum extent possible, the Department will endeavor to assure the broadest representation in the selection of technical advisors consistent with the basic obligation of serving the primary statutory objectives involved.

Institutional Accountability

The Committee notes that effective systems of accountability are lacking in many grantee institutions. In this connection, the Committee observes that systems utilizing modern accounting and auditing methods, central purchasing, inventory management, and other basic business techniques are needed to provide meaningful stewardship of Federal grants. The Committee expresses favor for the principle of enlarging the management role of grantee institutions, provided that (a) individual institutions are equipped to discharge effectively the added responsibility and (b) the decisions involved can properly and effectively be made by grantees. The Committee emphasizes that ways must be found to encourage institutions to assume more initiative and responsibility in the management of Federal grants, but also indicates its uncertainty as to just what incentives would facilitate this process. Because institutional forms of support assume a high degree of responsibility on the part of grantees to administer with prudence the Federal funds involved, the Committee makes Recommendation No. 17:

" . . . that the percentage of grant funds allocated to the general research support program not be increased, and no new forms of institutional support be initiated, until (1) PHS has modified GRS policies for a more equitable and efficient distribution of these funds, as recommended earlier in this report, and (2) PHS or HEW is prepared to promulgate grants management standards and to determine that institutions wishing to be eligible for research support are in compliance with those standards."

Without question, the grant relationship imposes upon the grantee clear responsibility for the effective management of the funds awarded in the accomplishment of the purpose for which the grant was made. The statement of principles governing the use of grant funds by grantee organizations promulgated by PHS makes this fundamental condition clear in the following statement: (34)

" . . . Under the terms of a research grant, the institution and the principal investigator enter into a special relationship with the Public Health Service for the utilization of grant funds. This relationship results from the basic nature of the grant as a conditional gift in response to a request for support of a project in which there is a substantial measure of public interest.

"A grant, therefore, represents a mutual joining of interests on the part of the grantor and the grantee institution in the pursuit of a common objective. In this relationship, the grantee institution assumes with the grantor the obligation to act in the public interest in achieving a common purpose. This is a relationship of trust which imposes upon the grantee institution the responsibility to assure that the grant funds are utilized for the purpose for which they were awarded, and to exercise the same probity and prudence in their expenditure that is extended to the use of the grantee institution's own funds."

Thus the Department is in full concurrence with the objectives being sought in the Committee's discussion of the problems of institutional accountability. The nature of the relationship that exists between a Federal agency and a nonfederal institution that applies for and receives a grant for a particular purpose has never been explicitly elaborated in law. The Department has directed much attention to this matter as representing a prime consideration of public policy and has attempted to set forth its views of this relationship to the Congress in various congressional hearings (35,36).

The matter of concern for the Department that arises in connection with the Committee's discussions of institutional accountability is the implication that the recipient of a grant, to meet the obligation for prudent management, is required as an absolute condition of support to give evidence of the existence within the grantee institution of formal management systems utilizing modern accounting and auditing, central purchasing, inventory management, and other basic business techniques. As the Committee is well aware, authority to make grants involves an explicit Act of Congress. Thus, the grant is viewed as a special instrument of public action. It is distinguishable from a contract in that it does not constitute the procurement of goods or services required for the performance of public business. In contrast, it is a unilateral act centered in the concept that the public interest will be served by contributing to the work of a nonfederal organization. Thus the primary concern in making a grant is the identification of the public value to be gained through the grant and the capability of the awardee to advance such value. The determination of whether the public interest has been so served is not in the nature of the expenditure that is made under the grant, but in the degree to which the broad objective being sought has indeed been furthered as a consequence of the award.

Thus the Department believes it to be in the public interest to reserve a substantial degree of flexibility in the conditions bearing upon the award of a grant. Agencies should not be precluded from making grants to an established nonfederal institution otherwise suitable unless there is compelling evidence of the institution's inability to exercise prudent stewardship over Federal funds. The Department is fully conscious of its responsibilities not to make awards to irresponsible individuals or institutions.

The Department is also aware of its obligations to extend the capabilities of grantees to perform responsibly in the use of granted funds. In this respect the Department is extending efforts to cultivate and assist in the development of sound managerial resources in its grantee institutions. The PHS study directed towards the feasibility of enlarging the grantee institution's role in the management of research projects is but a part of that process. Another element is the establishment of an advisory committee of university business administrators as a means for the Department to work directly with the management representatives of grantee institutions in enlarging current grant-management capability on their part. This process will be a continuing one, and the Department is convinced that good progress is being made.

In respect to Recommendation No. 17, however, the Department is convinced that it would be unwise to establish any absolute degree of management capability on the part of a grantee institution as an explicit condition of eligibility for research support. This must continue to be a variable judgment encompassing both the nature of the public purpose to be served and the assessment of this Department of the capability of the institution for prudent use of the funds involved. This view, however, will not diminish the efforts of the Department and its constituents to contribute to the managerial capability of the framework of nonfederal institutions upon which the progress of its grant programs depends.

Appendix: Part A

Health Research, Inc.--Overpayment of Indirect Costs

1. Background

Since the NIH payment to Health Research, Inc., of the maximum indirect-cost rate allowed by statute has been cited by the Committee as an example of weak management by NIH, some background information is relevant. Health Research, Inc. (HRI), represents a unique situation for NIH, since it is the only institution to which NIH has awarded grants on so large a scale which--

- is a State-Government related, noneducational research organization;
- is a noneducational institution operating largely in State-owned facilities and using other State resources; and
- has been billed for a substantial amount for NIH overpayment of indirect costs.

Prior to 1963, when the question of recovering overpayments from Health Research, Inc., was first raised, that organization was under the impression that the NIH funds it received for indirect costs were based on a fixed percentage for which HRI would not have to account specifically in its records. This view should not seem particularly strange, since it precisely coincided with the previously mentioned recommendation of the Elliott Committee (37). HRI informed NIH that if it had been advised of the provisional nature of its rate, it would have changed its accounting and fiscal practices in order to record adequately the costs attributable to the use of the facilities and other resources of the State of New York. HRI maintained that such resources, provided for its use by the State, are not ipso facto available gratis to outside sponsors of its research programs. It has further maintained that it accepted low rates for contract purposes, exclusive of State costs, only because the contract work in comparison with its grant program, both Government and non-Government, was insignificant at the time and did not warrant changes in its fiscal and accounting procedures necessary to compute and include the costs in its overhead determination.

2. Previous Relationship Between HRI and the State of New York

The question concerning paying HRI for costs incurred on its behalf by New York State, however evident the problem of the treatment of such costs may now seem, did not arise for some years after HRI began receiving NIH grants. It was not until June 25, 1963, that the Office of the General Counsel advised NIH regarding the difficulty over the legal relationship of Health Research, Inc., to the Government of the State

of New York, and especially of the question of the proper determination of the indirect cost of HRI.

(In respect to this relationship between HRI and New York State and the question of paying the former for the indirect cost incurred at the expense of the latter, DHEW is now facing a comparable problem where other separately incorporated research foundations and their affiliated educational institutions are concerned. Though the condition has existed for some time, it was not considered significant by DoD. Nevertheless, the legal question has now arisen as to whether a research foundation may be paid from grants and contracts for indirect costs incurred by its affiliated university on research performed for it by the university if the foundation does not actually pay for these costs. As with HRI, the question is not whether the expenses are incurred but whether the grantee has a right to be paid for them from the grants. The matter is of much concern to the interested parties, and its solution is being vigorously pursued both by the institutions and the Office of the Secretary, DHEW.)

3. Current Relationship Between HRI and the State of New York

It should be noted that HRI is now paying New York State for the costs incurred by the latter on its behalf; consequently, there remains no question that HRI is now entitled to reimbursement for these costs, although the expenses are no more actual now in the composite frame of HRI and New York State than before. The HRI indirect-cost rates have increased greatly due to the inclusion of State-owned facilities and resources now paid for and recorded on the books of HRI, and due to new and additional administrative activities necessitated by its overall growth and improvements in its administration of grant programs, cost accounting, etc., as required by NIH.

4. Present Fiscal Situation of HRI

In an attempt to keep pace with its rapidly increasing fiscal requirements, HRI has proceeded since 1964 to modernize its administrative practices. This modernization has included the conversion from an outmoded accounting system to an IBM computer-based system. NIH regards these steps as indicative of good faith on the part of HRI in attempting to resolve its difficulties. However, this accounting modernization has been the source of still further difficulties for HRI; as a result, the conversion to a computer-based system with its attendant problems has contributed heavily to the late submission of reports of expenditures and indirect-cost proposals by HRI.

Actual indirect costs (and rates) for HRI, as mentioned above, have increased in recent years as a result of including State-owned facilities and resources, now paid for and recorded on the books of HRI, and also due to new and additional administrative activities necessitated

by the overall growth and improvements in its management of grant funds (e.g., cost accounting procedures) and other activities required by NIH.

As the Committee states, indirect-cost payments made during fiscal year 1964 and through December (1964) of fiscal 1965 were based on provisional rates which may prove to be in excess of the audited rate. However, the actual rates for those years will undoubtedly be substantially higher than the last audited rate for HRI. In addition, possible overpayments are likely to be considerably offset by subsequent underpayments, which may have resulted from the application of lower provisional rates based on the earlier and lower audited rate.

5. Recovery Made by NIH of Overpayments Through 1963

Earlier indirect-cost overpayments to HRI of \$412,208.06, covering the period fiscal 1958 through fiscal 1963, have been recovered by NIH through the withholding of current payments in September 1965, and these funds have been returned to the United States Treasury. It would be inappropriate at this time to attempt, beyond present efforts, to collect possible overpayments made during fiscal 1964 and 1965 until accurate information is available from HRI's public accountants and from its new computer system.

6. Need for Current Indirect-Cost Rate for HRI

NIH has adopted this position as a result of the financial difficulties experienced by HRI, in part attributable to the withholding of current payments to offset earlier overpayments. Its difficulties also stem, in part, from the fact that HRI has been unable to have its recent indirect-cost payments adjusted to represent more nearly its current indirect-cost rate. This is attributable in part to its failure to submit timely indirect-cost proposals (due to conversion to a computer system) and partly to lack of current Government audits.

The Government audits at HRI have been delayed partly because of the reorganization of audit functions in the Department of Health, Education, and Welfare and the Department of Defense. In particular, they were delayed to allow the General Accounting Office to complete its audit made at the request of the House Subcommittee on Intergovernmental Relations. The NIH has only recently received the report of the GAO audit team, but to comment in detail on its contents would be inappropriate at this time.

7. High Quality of HRI-Managed Research Programs

Throughout this consideration, it should be kept in mind that Health Research, Inc., in reality represents the State of New York in dealings with the Federal Government involving two excellent research institutions,

the Roswell Park Memorial Institute (Buffalo) and the Division of Laboratories and Research (Albany). While NIH certainly does not condone the awarding of Federal funds to which an institution is not entitled, neither does NIH wish to harm by its actions the organizations actually performing high-quality biomedical research with NIH support. NIH's honest attempt to mold these objectives into a workable and prudent policy has admittedly not resulted in administrative tidiness in this case. Nevertheless, NIH adheres strongly to the position of doing no harm to these research institutions, as long as HRI continues to improve substantially its accounting and administrative staffing and related systems and procedures. These improvements are expected to decrease the lag-time in submission of required reports and records and thereby to enhance its fiscal responsibility. Health Research, Inc., continues to be the choice of the State of New York to act as its fiscal agent for the receipt of Federal funds. NIH does not consider it appropriate for the Federal Government to interfere in the organizational affairs of a sovereign State in this matter.

Appendix: Part B

Health Research, Inc.--General Research Support Grants

The problem of HRI, Roswell Park Memorial Institute, and the Division of Laboratories and Research is complex. The substantial funding of research by NIH in these institutions attests to their scientific competence. Roswell Park Memorial Institute is in the first rank of organizations, academic or otherwise, engaged in research on neoplastic disease, a category responsible for over 300,000 cancer deaths each year in the United States. The Department feels that NIH made a conscientious attempt to resolve the problems surrounding the award of General Research Support grants to these organizations in accord with the intent of legislation which established the GRS.

The crux of the matter is that the Buffalo Division of HRI was indistinguishable from Roswell Park Memorial Institute in terms of the major concern of NIH--namely, its health-related research program. Likewise, in terms of scientific program content, the Division of Laboratories and Research was indistinguishable from the Albany Division of HRI. At the level of execution of research projects, funds both from the appropriations made by the State of New York and from research grants from NIH and other Federal and non-Federal agencies were used in common purpose. Thus, the legislative intent--which program guidelines were designed to subserve--would presage an award which gave due weight to both Federal and non-Federal expenditures. The administrative problem was to meet the imperatives of equity in a situation in which either an oddity of corporate organizations--necessitated by local circumstances--or a self-defeating program guideline stood in the way of fair and equitable action.

In 1963 and 1964, consonant with the then prevailing policies of the program and the knowledge then available to the staff, awards, as described in the Committee report, were tendered to HRI-Buffalo and HRI-Albany. However, the 1965 award took cognizance of a ruling by the General Counsel, DHEW, which stated that HRI should be regarded as a separate legal entity, distinct from the State agencies (RPMI and DLR); expenditures by the State agencies from State appropriations were disallowed in HRI's entitlement claim. Further, in 1966 only one application was accepted, and included expenditures made by both HRI-Albany and HRI-Buffalo as entitlement claims.

In connection with the application for FY 1967 funds, extended discussions between NIH and HRI revealed much new information, on the basis of which it now appears that the greatest consonance with the legislative intent of the GRS program would be achieved by making awards to the two

eligible components of the New York State Department of Health, the Roswell Park Memorial Institute and the Division of Laboratories and Research. Each award was therefore based on the total research expenditures of each of these institutions including those derived from Federal sources--predominantly NIH through HRI--and from non-Federal sources, predominantly the State of New York.

Officials of the RPMI and the DLR requested that payments on the grants be made to HRI, as fiscal agent for the GRS grants being awarded. NIH agreed to do so, since this was consistent with previous actions by NIH on grants awarded to universities, where the applicant requested that an affiliated foundation receive the grant payments and serve as fiscal agent, and since legal responsibility for the grant funds awarded remained with RPMI and the DLR because HRI was only acting as an agent under each grant.

As a matter of convenience to the institutions, the Federal payments are made to a fiscal entity known as HRI. The fact that payment is to HRI in no way vitiates the inescapable reality that research projects--which in toto constitute the research program of each of these institutions--are performed with funds derived from both Federal and non-Federal sources. Payment to HRI in no way affects the scientific, legal and administrative responsibility of the New York State Health Department for the use of grant funds.

A detailed review of the record of this case, in the opinion of the Department, reveals a high degree of administrative responsibility and sensitivity. It provides strong evidence of continuing sharp focus on program objectives and legislative intent and will indicate that, where ambiguities or uncertainties based on lack of information existed, program administrators resolved the issues in the public interest. Program officials, in the light of previously unavailable information about HRI, have recently taken what they believe to be the correct course of action, even though it involved a reversal of an earlier position, and at least potentially, opened NIH to criticism for inconsistency.

In the view of the present knowledge of the existing situation and the recommendation with respect to funding in 1967 which the National Advisory Health Council consequently approved after careful consideration, it would now appear that these institutions had received a disproportionately small share of funds appropriated in 1965 and 1966, rather than--as the Committee believes--a disproportionately large share of funds appropriated for 1963, 1964, and 1965.

Appendix: Part C

Departmental Position on the Recommendations of the House Committee on Government Operations

Indirect Costs Overpayments

"Recommendation No. 1.--The Committee strongly recommends that the Surgeon General make suitable arrangements to assure the uniform application of the Department's indirect cost rate information by all granting units of the Public Health Service. With respect to the use of off-campus rates, which are normally lower than on-campus rates, the Committee recommends that the Public Health Service obtain sufficient information in grant applications and in subsequent reports to identify the locations at which the research is performed."

In respect to Recommendation No. 1 of the Committee's report, the arrangements proposed therein have already been accomplished. A system to assure the availability of indirect-costs information and uniform policies in its application throughout DHEW has been established. Provision has been made for securing additional information on the location of research activities, to assist in ascertaining the application of differential off-campus indirect-cost rates.

Despite the progress in this area, the handling of indirect costs continues to present policy and operating problems which are now under study to permit further improvement:

1. Because of the varying sources and currency of indirect-cost rates, and the varying character of research projects, available rates may not be directly and simply applicable, presenting continuing problems to program administrators involved in determining the amounts of awards.
2. Increasing costs and the changing administrative arrangements in institutions limit the durability of a given rate and the extent to which use can be made of the fixed-predetermined rate method of paying indirect costs authorized by P.L. 87-638. This forces continuation of the process of making provisional allowances for indirect costs, with the consequent burden of recalculations and adjustment. The Department is endeavoring to extend use of the fixed, predetermined rate method in administering indirect-cost activities.

3. The determination of the appropriate circumstances for the use of "off-campus" indirect-cost rates can be extraordinarily complex. Various factors enter into whether an off-site rate should be used. A specific study is now under way aimed at developing criteria for establishing off-site rates and the mechanics for identifying the circumstances where such rates should be applied.

Improving Indirect-Cost Determination

"Recommendation No. 2.--The Committee endorses the concept of assigning Government-wide responsibility for establishing indirect cost rates with all institutions of a given type to a single Federal agency, with each type of institution audited by one Federal agency only. The Committee recommends that this concept be vigorously pursued by the Bureau of the Budget and other interested agencies so that a final Government-wide plan covering all institutions will expeditiously be established."

While deferring to the primary responsibility of the Bureau of the Budget in respect to Recommendation No. 2, it should be noted that the Department has long advocated this objective and sought to engender its exploration. Thus DHEW is in full accord with this recommendation.

General Research Support Grants

"Recommendation No. 3.--To eliminate some of the abuses that have developed in the general research support program, the Committee recommends that program policies be changed immediately to:

(1) Determine each GRS grant on the basis of the recipient institution's research expenditures from Federal sources alone. The Committee does not believe the premium given for non-Federal research funds under the existing formula operates as a meaningful incentive for institutions to seek private funds. Rather, this premium favors research organizations over institutions of higher education, and has been difficult to administer and wasteful of Federal research money, and

(2) Exclude from the computation base for a GRS grant all Federal payments for research which include fees above actual research costs.

Additional recommendations concerning the GRS program appear below."

In respect to Part I of Recommendation No. 3 of the Committee report, the Department has directed PHS and NIH to submit to the Secretary a plan for modification of the formula utilized for calculating the awards under the General Research Support Grant program which provides for the elimination of the premium factor for nonfederal research expenditures, as well as other changes considered desirable, to be effective with the GRS awards made for fiscal year 1969. This plan would encompass such interim arrangements as may be necessary to moderate abrupt changes in the magnitude of grants now being received by institutions whose entitlement may be substantially affected by the revised formula.

In respect to Part 2 of Recommendation No. 3, instructions have been given to PHS and NIH to require institutions to exclude as entitlement claims for GRS awards all Federal research contract funds which include fees above actual research costs. The amount of specific fees on such contracts are, under present policies, excluded from the entitlement calculation. In view of the Committee's concern of the data furnished in respect to the Stanford Research Institute, PHS and NIH have also been directed to take appropriate action to the extent that applicable policy and practice in respect to contract fees have not been observed.

Health Sciences Advancement Award

"Recommendation No. 4.--The committee strongly recommends that no future grant programs be initiated by NIH or the Public Health Service without fair and open competition after the purpose and the policies of the program have been carefully developed and publicly announced.

"Recommendation No. 5.--The committee further recommends that before any new grant program is started, or a major change is made in the existing program, the proposed regulations for the program be published in the Federal Register so that interested parties may have an opportunity to express their views. The final regulations should be approved by the Secretary before issuance.

"Recommendation No. 6.--The committee recommends that before any new program is initiated in the Public Health Service without specific statutory authorization, the program should be formally reviewed by the Department and the Executive Office of the President to determine its conformance with national education and science policies. Also, a written opinion concerning the legality of any such program should be obtained in advance from the HEW General Counsel.

"Recommendation No. 7.--The committee further recommends that no additional HSAA awards be made unless and until PHS obtains specific legislative authorization for this program."

As a matter of general practice, vigorous open competition governs awards of the funds appropriated to NIH for research project grants, training grants, fellowships, and facilities construction grants. Programs such as these, once well established, publish statements describing their objectives, eligibility requirements, application formats, and the process for review and approval. When features distinctive enough to require amendment of the PHS regulations emerge, the prescribed formalities, including publication of contemplated changes in the Federal Register, are observed.

Thus, NIH has long respected and prized the tradition of public administration that gives all potentially eligible claimants equal access to appropriated funds. In the administration of NIH Research Grant programs, elaborate machinery has been developed over time for informing potential applicants, for the filing of applications, and for subjecting these to careful review according to clearly understood criteria of scientific merit and program relevance. But it is important to note that this widely known and respected framework emerged only after considerable experimentation and progressive modification based on experience. Throughout this period new program developments were initiated in limited trial forms as a basis for assessing the validity of the concepts involved and the procedural adaptation required. From

such tryouts the basis for broader efforts and information required for adequate public announcement was formulated.

It seemed clear, after careful consideration, that the best interests of the Government and the academic community would be served if a similar approach were exercised in the experimental phases of the HSAA program. Initiation of such an experiment on a small-scale basis appeared to be an approach that would lay the groundwork for a soundly conceived formal program when and if expansion on a national scale could be justified. After first-hand experience had been garnered, program objectives as well as the policies and procedures for attaining them could be defined in terms of greater precision and specificity than those general ones which were the best possible within the existing state of knowledge. The rationale for establishing the eligibility requirements for various classes of institutions would also become more evident.

In the event that the feasibility study did not yield encouraging results, a pilot program launched cautiously, pragmatically, and without extravagant promises could be terminated before large sums of money had been committed. For while large awards to potential "centers of excellence" might turn out to be useful to the grantee and to the Nation in important ways, they would only be justifiable under this program if they produced the "quantum" increase in capability required to establish a true center of excellence in the health sciences.

Thus, the Department is persuaded that the conditions which prevailed at the time justified NIH's exercise of limited experimental option even though the number of institutions involved might have been larger. Beyond undertaking what amounts to pilot efforts under appropriate terms, the Department concurs fully with the general procedure advocated implicitly in the Committee's report: that new formal programs be inaugurated after public announcement and with open competition.

Therefore, the Department's reaction to Recommendation No. 4 is concurrence in general, but with clear recognition that under exceptional circumstances, such as those prevailing at the time the HSAA program was inaugurated, the constituent agencies of DHEW must be permitted the flexibility under appropriate Departmental guidelines to experiment with imaginative and creative program innovations so essential if national needs are to be responsibly served.

The acceptability of Recommendation No. 5--for the publication in the Federal Register of the proposed regulations for new programs and the major changes in regulations for existing ones--depends on the definition of "new" and "existing." The Department would have no objection to supplementing the highly effective public announcement procedures traditionally employed by NIH with use of the Federal Register when it has been determined that new programs (1) have completed their experimental phases, (2) have encountered and solved the major administrative problems that usually appear during early operational phases of novel endeavors, and

(3) have been expanded to a significant scale. Until such time, an agency needs maximum flexibility to be responsive to unexpected situations, and needs freedom from ponderous and formalistic procedures in order to modify policy rapidly in the light of lessons taught by operating experience.

The use of standing and ad hoc advisors and advisory committees, and of National Advisory Councils, has been a very effective mechanism for soliciting the opinions and the reactions of interested parties. In the same context, major changes in existing programs, when important, widely applicable, based on extensive experience, and viewed as relatively permanent, should also be published in the Federal Register. Standard procedure, of course, requires the Secretary to approve and issue such regulations.

Statutory Authority. The concerns of the Committee on this score take two forms: a challenge of the adequacy of existing authority, with the implication that administrative actions taken by NIH in starting the program were illegal; and an insistence upon the need for explicit statutory authorization for the HSAA program.

The legislative history of Public Law 86-798, which authorized grants for general support of the research and research training programs of certain classes of institutions, clearly envisaged the broad exercise of discretion in the design of detailed instruments to carry out the purpose of the law. However, the adequacy of the statutory authority for the program was challenged in the spring of 1967 in the process of examination by the Committee on Appropriations of the U.S. House of Representatives of the President's budget requests for fiscal year 1968. As a result, first the Office of the General Counsel for the Department of HEW and then the Comptroller General of the United States were requested to rule on the question of adequacy of the existing legal authority to operate the Health Sciences Advancement Award program. Each of these offices affirmed that the authority conveyed in the General Research Support statute (P.L. 86-798) was adequate for the action taken.

The Department, as a consequence of these opinions, believes that the requirement of specific statutory authorization for the HSAA program has been met. Thus Recommendation No. 7, which is predicated on a contrary assumption, must be considered as inapplicable.

The Department agrees with the objectives inherent in Recommendation No. 6 that new programs be "formally reviewed by the Department and the Executive Office of the President to determine its conformance to the national education and science policy." The formal process of the development of the budget requests requires both program examination and concurrence by the Department and the Bureau of the Budget. Thus it may be reasonably inferred that this program was in "conformance with national education and science policies."

Single-Instrument Support:
The Sloan-Kettering Award

"Recommendation No. 8.--The committee recommends that the Congress amend this provision of the act to clarify and limit the Surgeon General's blanket authority to adopt 'such additional means as he deems necessary or appropriate' for the conduct and support of research."

To be able to act in exceptional circumstances, and to undertake special arrangements in furtherance of research, not only in cancer but in comparably urgent and difficult health problems, are viewed by the Department as essential provisions of law for the discharge of national responsibilities in the health area.

Thus the Department does not support the Committee's recommendation that Congress amend this provision of the Act with the intention of limiting the authority, now resident in the Secretary of HEW, to undertake such necessary and appropriate action in respect to the conduct and support of research in matters related to health and disease.

Because of the breadth of this authority, however, the Department concurs in the view that it should be exercised only after careful consideration of the circumstances involved. To assure that such careful consideration precedes such action, the formal delegations of authority within the Department are being reviewed to assure that there are appropriate restraints on the use of this authority.

Quality of Research

"Recommendation No. 9.--The committee recommends that the Surgeon General establish a high standard of quality as the basic qualification for research project support, and that he develop adequate procedures for the uniform maintenance of that high standard by NIH and other bureaus of the Public Health Service. The confinement of research grants to projects in the range of excellent to good should not be breached except in special circumstances where the reasons for supporting a lower quality project are fully documented in a written record."

The support of investigator-initiated research projects through the Regular Research Grant programs of NIH is a major and long-standing component of NIH operations. What is expected of the individual investigator under this program of NIH is the sine qua non of science: to propose scientifically meaningful research of the best that he is capable. A scientist can do no less. The selection of such projects for the award of grants is through a process that assigns determinant roles to peer groups, notably study sections and advisory councils. This review system, which derives from the statutory requirement for affirmative advisory council recommendations prior to award, constitutes a truly unique achievement in meshing the considerations of public purpose with the criteria and values of science in the conduct of Federal programs. The process has been subjected to numerous critical examinations and broadly judged to be sound, effective, and conducive to the interests of both science and public.

The standards of this process are rigorous. The result: As the number and dollar value of research grant applications has increased, the proportion of applications surviving this review has fallen. In recent years almost half of all the new and 40 percent of the competing research grant applications received by NIH have failed to pass the basic qualitative threshold and have been disapproved. The following charts show this trend graphically.

The priority scores utilized in the review process are assigned to applications only after they have been approved by a study section. Thus, the scientific merit of a project and its eligibility for NIH support have already been established. The purpose of the priority score is less to quantify quality in an absolute sense than to provide a means of gaining a collective opinion of the reviewers for ranking the applications recommended for payment. This is not to suggest that priority rating is unrelated to scientific merit, but other subjective variables are reflected in these numerical indices. To illustrate: Given two project proposals of corresponding scientific merit, one an epidemiological approach, another a laboratory technique, one reviewer might assign higher priority to the former as a consequence of his conviction that the "state of the art" in that science-discipline calls for more emphasis on epidemiologic studies. Thus, priorities reflect scientific choice

as well as scientific merit.

In 1956 the NIH appropriation for project-grant support was \$40 million, which represented 13 percent of the estimated total national expenditure on medical research (\$312 million) and involved the support of only 2500 projects. The national need was great and the research capacity of the Nation substantial; national programs were severely limited (partly because of the Korean war); and only established investigations, research programs, and institutions were being supported. The skewing of priority ratings to the upper end of the scale during the period when these conditions were in substantial dominance was inevitable.

Ten years later that universe of medical research was transformed. National expenditures in this area totaled over \$2.0 billion, of which the Federal share was \$1.3 billion and the NIH figure was \$791 million, the predominant share of which was expended in support of almost 16,000 research projects. These are the dimensions of a national medical research effort which is not only of a wholly different order of magnitude, but is beyond equating in respect to the scope and depth of the science involved or the investigators and institutions engaged, and to the extent to which the national interests are being served. To ignore these massive changes and to assume that the priority rating pattern of 1956 is a valid base of comparison with the pattern of 1966 hardly seems reasonable.

Furthermore, it would be difficult, indeed, to demonstrate any meaningful change in the priority character of research grant applications after the initial period of rapid program growth. Thus, since 1960 the distribution of priority scores--as shown by the table printed in the Committee's report--has remained virtually constant with:

- about 24 percent in the 100-199 group,
- about 48 percent in the 200-299 group,
- about 25 percent in the 300-399 group, and
- only 3 or 4 percent in the lowest priority category of 400-500.

In 1966 and 1967 the proportion in the highest priority group has shown a distinct increase, to 26 percent and 30 percent respectively.

As a consequence of its examination of all the considerations surrounding the Committee's comments on the quality of research being supported through NIH programs, the Department concludes, as noted at the outset of this discussion, there has not been a "continued lowering of research standards" in the conduct of these programs nor has "a much lower level of competence . . . replaced high quality as the standard for determining whether research is worthy of Federal support." The available evidence, to the extent that it can be considered to reflect qualitative trends, suggests quite the opposite trend.

Thus, in respect to the Committee recommendation that a high standard of quality be the basic qualification for research project support and that adequate procedures be developed to maintain that standard, the Department believes that the existing arrangements have given and will continue to give firm assurance that only projects worthy of public support for the accomplishment of the statutorily established objectives of NIH programs will be awarded grants.

In respect to that part of the recommendation relating to the circumstances under which projects fall in the lower priority ratings, present procedures require that any application falling in the lowest 10 percent of the priorities assigned by any Study Section be subjected to special review by staff and the relevant Advisory Council before an award is made. This process assures that applications receiving the lowest decile of priority ratings are thus deliberately selected for their importance to some aspect of the relevant Institute's program. This procedure has been in effect since June 1959 in response to criteria set by President Eisenhower.

Concentration of Grants

"Recommendation No. 10.--The committee recommends that the Public Health Service's responsibility for programs designed to develop or improve the capability and resources of educational institutions be limited to medical and other health professional schools. The general research support program is not included in this category since the Congress authorized these grants, permitting broad discretionary spending, specifically to supplement project grants. The committee recommends that the responsibility for grants intended to strengthen educational institutions other than health professional schools be confined to the National Science Foundation and/or the Office of Education--the two Federal agencies broadly responsible for strengthening basic science and education."

A policy that would limit NIH efforts to improve the health-related research capability and resources of educational institutions to medical and health professional schools would not be compatible with the realities of existing Federal-university relationships, nor with the scope of science upon which the advancement of health capability depends.

The last several decades have seen the evolution--principally in non-health professional components of graduate schools--of hybrid scientific disciplines such as biochemistry, biophysics, and biomathematics into strong and viable areas of scholarly endeavor. These new sciences represent points of contact and areas of interdigitation between the sciences of chemistry, physics, and mathematics and that of biology. New knowledge developed in these hybrids, particularly in specific subdisciplines, has proved to be enormously significant for health. There is every reason to believe that fundamental insights into health problems will continue to flow from these sources.

The Department believes that there are important and noncompetitive developmental roles to be played by NIH, NSF and OE in the non-health professional components of this Nation's graduate schools in the present context of national policies and arrangements for support of university functions. OE's mission is the broadest and most general--to support the basic process of graduate education and the basic educational enterprise. NSF has primary responsibility for education and basic research in the sciences generally, including mathematics and engineering. And NIH must focus on research and research training in the sciences related or oriented to health.

Thus, in respect to the Committee's recommendation that NIH's programs directed towards the improvement of the capability and resources of educational institutions in the biomedical area be confined to medical and other health professional schools, this Department believes that such modification would impair the achievement of national objectives in the area of health and medical research in the present context of Federal relationships to educational institutions.

Aiding Weaker Institutions

"Recommendation No. 11.--To provide for more equitable treatment of the smaller and less wealthy institutions, the committee recommends the following changes in PHS policies:

- "(1) Qualification for a GRS grant should be based on a school's receiving \$100,000 or more annually in research project grants from all units of the Public Health Service combined, rather than exclusively from NIH. Moreover, HEW should consider broadening the GRS program, with appropriate legislative authority, to include health-related research grants made by other units of the Department in such programs as vocational rehabilitation and maternal and child health. Eventually, a single general research support grant for each eligible institution, administered on a Government-wide basis, would be most efficient and desirable.
- "(2) The amount of each GRS grant should be determined solely on the basis of the institution's research expenditures from Federal sources. The committee does not believe the premium given for non-Federal research funds under the existing formula operates as a meaningful incentive for attracting private funds. Rather, this premium discriminates against poorer institutions, favors research organizations over institutions of higher education and, as demonstrated in chapter IV, has been difficult to administer and wasteful of Federal research money.
- "(3) The same GRS eligibility requirements should be applied to health professional schools as to other institutions. To the extent that health professional schools require assistance in developing a research capability, this should be accomplished by a separate program of technical and financial assistance tailored for the purpose.
- "(4) The separate biomedical sciences support grant should be discontinued, and the GRS grant awarded to graduate schools on the same terms as to professional schools, hospitals, and research institutions.
- "(5) Until such time as a single general research support program may be established on a Government-wide basis, the NIH program and NSF's institutional grants program should be closely coordinated to avoid duplication. Some institutions

presently receive general research support from both NIH and NSF computed on the basis of the same research projects; this occurs because NSF bases the amount of its award exclusively on the research (as well as some research training) grants it makes, while NIH includes these same NSF research grants in the computation for GRS awards."

As noted in the prior section of this response dealing with General Research Support program, this program was designed to provide support for the health research and research training programs of institutions and thus to complement project support for individuals within those institutions. Its major intents were to provide funds to redress imbalances and inflexibilities created by categorically oriented research-project grants; to foster autonomous institutional growth in the health sciences area through the development of research and research training programs in accordance with self-defined institutional aspiration; and to create and operate the central resources and facilities used in common by many biomedical scientists within the institution.

In evaluating the meaning of "equitable" utilized by the Committee, one should not lose sight of the fact that intrinsically the GRS program is discriminatory. It was intended, within limits, to provide support in proportion to the imbalance or straining of institutional programs by categorically oriented research-project grants from NIH. Institutions were not to receive awards unless a reasonable basis was evident to conclude that such distortion operated. Hence, a threshold, defined in terms of dollar amount of NIH support, became a necessary (but not sufficient) requirement to be met in establishing institutional eligibility.

The intent of these remarks is to introduce a note of caution into the formulation of the concept of "equitable treatment" when applied to the "smaller and less wealthy institutions" under the GRS program.

Thus, in respect to the general purpose of Recommendation No. 11, the Department shares the concern expressed in the Committee report for institutions which are small, or modestly endowed, or outside geographic areas of high-population density. With the Committee, the Department believes it to be in the national interest to upgrade the research capability as well as the general excellence of all classes of institutions of higher learning. However, the Department is persuaded that the fundamental considerations involved in seeking this objective are so different from those toward which the General Research and Biomedical Support programs are directed that, as noted above, a broader national program should be devised for this purpose.

In respect to the specific components of Recommendation No. 11, many of the changes proposed are ones that have been under consideration within the Department. If the Report of the National Academy of Sciences-National Research Council evaluative study of the General Research Support program had not cautioned against such action before at least 1967, and were it not evident that some of these actions, if taken precipitously, would have serious adverse effects on specific institutions, several of these recommendations would have been put in force some time ago.

The Department concurs in principle with the Recommendation 11(1) that the eligibility base for general research support be broadened beyond the present NIH base. Plans for effecting this will be developed within the coming year. With regard, however, to expanding this program to make possible a DHEW-wide and, eventually, a Government-wide general research support program, the Department has misgivings. These derive from the conviction that the changes would inevitably reduce the effectiveness of these funds in achieving the statutory missions of the separate Federal agencies which support research and development efforts in their respective fields of interest in eligible institutions.

The Department concurs in principle with Recommendation No. 11(2), the effect of which is to terminate automatic eligibility for those classes of health professional schools initially declared eligible when the program began in 1962. However, it reserves the right to put this change into effect in such a way as to minimize dislocation and adverse effects in grantee institutions, and further hopes that new authorities and funds will become available to develop research capability and otherwise strengthen some of the previously eligible institutions which need and have no other source of such support. Particular consideration will be given to the problems of these institutions in the legislative submissions that relate to the extension of the Health Professions Educational Assistance Act.

The Department wishes to study more carefully Recommendation No. 11(3), to discontinue the Biomedical Sciences Support Grant program. The view at NIH is that there should be as many fund-allocation formulas as there are homogeneous classes of institutions in terms of institutional importance as a performer of health-related research. It may turn out that no distinctions sufficiently important to warrant separate categorization should be made, in which case the recommendation will be accepted. Alternatively, two or even more programs may appear most appropriate.

The Department concurs in Recommendation No. 11(4) that there be close coordination between NIH and NSF in the evolution of their respective programs of the type that NIH calls general research support. At the moment they are the only sources of Federal support for such programs. It should be noted that coordination has been practiced in the past, even though differences of opinion--which the NIH believes to be entirely appropriate--on some problems continue to exist.

As noted in response to Part 1 of Recommendation No. 3, this Department has directed PHS and NIH to submit to the Secretary a plan for the modification of the formula utilized for calculating the awards under the General Research Support Grant program which provides for the elimination of the premium factor for non-Federal research expenditures, as well as other changes considered desirable, to be effective with the GRS awards made for fiscal year 1969.

This plan will also take into account the foregoing recommendations of the Committee.

Training Grant Programs

"Recommendation No. 12.--The committee recommends, further, that the Secretary of HEW review the numerous NIH and other PHS training grant programs to determine if they are effectively organized to serve national manpower needs and objectives. This review should be concerned particularly with ascertaining if the institutions which receive large amounts of training funds are making a proportionate contribution to the nation's manpower supply. Conversely, the Secretary should determine if training grant policies discriminate against schools which award graduate degrees in the biomedical sciences but receive little or no PHS training support."

NIH training programs provide support for both predoctoral and postdoctoral training in the biomedical sciences. Approximately 65 percent of the support covers predoctoral training, with heavy emphasis upon the basic medical sciences, and about 35 percent covers postdoctoral training. Because of the inclusion of this significant postdoctoral training component, there is not necessarily a 1-1 correspondence between NIH training support and doctoral output in the basic medical sciences.

NIH training grant support is provided not only with respect to the intrinsic scientific quality of institutional programs, but also in terms of the relevance of the proposed training to the authorized mission of the awarding NIH Institute. It is not possible, therefore, for NIH training grant support to be provided to every environment simply because it awards advanced degrees in the biological sciences. Rather, training grant awards must continue to be made selectively on the basis of the twin criteria of scientific excellence and NIH mission relevance.

Nonetheless, the Department concurs with the Committee's view of the importance of assessing the effectiveness of NIH training programs in meeting urgent national needs for biomedical research manpower. Thus, in respect to Recommendation No. 12, the Department is directing the National Institutes of Health to extend its already broad and thorough review of the biomedical research manpower area now under way. The findings and conclusions of these studies are expected to be available during the forthcoming year. A subcommittee on manpower of the Advisory Committee to the Director of NIH has recently been established to provide guidance in the review of NIH training programs. It is anticipated that the advice and recommendations emanating from this group will also be of significant value in determining the appropriate NIH training role and responsibilities in the years ahead.

Technical Assistance to Institutions

" Recommendation No. 13.--The committee recommends that the President designate one or more Federal agencies to provide technical assistance, upon request, to help institutions plan for the improvement of their science education and research programs. It would be logical for the Public Health Service to be concerned with the health professional schools; other groups of institutions in which the biomedical sciences are taught might be made the responsibility of the National Science Foundation and/or the Office of Education."

While deferring to primary concern of the Executive Office of the President in respect to this matter, the Department wishes to emphasize that it has actively supported and participated in interagency efforts to this end and will continue to do so.

In respect to Recommendation No. 13, the Department feels that sufficient preliminary steps have already been taken by the Executive Branch so that it should be possible, within a reasonable period of time, to designate specific "cognizant agencies" for providing technical assistance in the development of academic science capabilities in respect to particular categories of institutions or areas of research. However, it is felt that it would be premature, pending the further development of these concepts, to make the division of responsibilities for the biomedical sciences suggested by the Committee.

Improving the Academic
Quality of Graduate Institutions

"Recommendation No. 14.--The committee recommends that the President give early attention to the problem of improving the academic quality of weaker graduate institutions and that a unified and coordinated Federal assistance program be developed for dealing with this matter. The committee believes the present piecemeal and uncoordinated approaches of Federal agencies to institutional improvement are competitive, wasteful, and frequently not directed to the heart of the problem."

Again the Department acknowledges the principal concern of the Executive Office of the President with this recommendation, and thus comments only from its more limited purview.

Graduate education is the culmination of the formal process of equipping individuals with the requisite scholarly capability for independent teaching, research, and technical endeavor at the frontier of expanding knowledge and technological innovation. As a consequence of the evolution of this academic function over the past 50 years, the graduate schools of the United States now encompass a predominant portion of the intellectual force of the Nation. This Department is convinced that only through the careful cultivation of this resource can the Nation be assured of continuing capability to advance knowledge, to extend the base for technological progress, to influence the social, cultural, and economic quality of national life, and to exert intelligent and effective leadership in world affairs. Gaining a national consensus on this fundamental circumstance constitutes the major challenge to Legislative and Executive efforts to bring about a more rational relationship between the Federal Government and graduate education.

Thus, in respect to Recommendation No. 14, the Department shares the Committee's concern with the problem of improving the academic quality of weaker graduate institutions. The Department emphasizes, however, that the existing circumstances are not solely the consequences of the diffusion of Executive responsibility in this matter, but are basically reflective of the yet ambivalent and indecisive state of the national mind in respect to the manner in which national action in this area will be taken and the policies which should govern. Nonetheless, a considerable effort is under way within the Executive Branch to improve existing conditions and to further the resolution of national policy in this area.

Central Management of Grants

"Recommendation No. 15.--The committee recommends that the Surgeon General (1) establish in PHS, and in each of the bureaus which administer grant programs, a single grants management office to provide uniform interpretations of policies and procedures, and (2) provide adequate staffing for PHS's Division of Grants and Contracts to enable this unit, on a current basis, to maintain surveillance over and liaison with the several bureau grants management offices to assure that policies are being properly and uniformly implemented."

In the initial section of Part II of this commentary, there is a review of the major efforts within NIH, PHS, and at the departmental level to advance the status and capability of the grants management function. The Department believes that substantial progress has been made in this area and that the framework is considerably stronger today than in the past. The Department would also re-emphasize its previous statement that there is no disagreement in respect to the responsibility that bears upon the Department and its constituents for sound management of grant programs.

Without question, an increase in competent grant management staff and further progress in the coordination of the necessarily diverse activities is required. Thus, in respect to Recommendation No. 15, the Department is in full accord with the objectives sought. The planned reorganization of the health functions of the Department now under study will provide both the opportunity and the means to focus and strengthen further the grant management activities of each of the constituent agencies.

Advisory Committees

"Recommendation No. 16.--The committee recommends that appointments to advisory councils be limited to one 4-year term, with members ineligible for reappointment, or appointment to other advisory councils, for a period of 4 years following the completion of their terms.

"The committee recommends further, that consideration be given in the selection of advisory committees to obtaining a balanced representation of geographic regions and educational institutions. To the extent possible, consultants should be drawn from among qualified scientists who are not themselves recipients of PHS grants."

The National Advisory Councils are unusual, if not unique, in that they are not only established by law but have the statutory authority to make recommendations prerequisite to the award of a grant by the Surgeon General. These Councils provide the basic mechanism for broad public participation in the programs of NIH. This unusual framework for joining non-Federal advisers in the direct conduct of Federal programs has been remarkably productive and has achieved complete acceptance by the scientific community. Indeed, much of the rate of growth, scientific distinction, and public appeal of NIH programs is directly attributable to this engagement of both lay concern and technical competence in program affairs.

Eligibility for reappointment, which is the subject of the Committee's recommendation for change, is covered by statute: reappointment of a member to the same Council is prohibited for one year following completion of a term of service.

Thus, in respect to Part I of Recommendation No. 16, the Department recognizes the need for rotation of membership on National Advisory Councils as the best means for insuring that interplay of fresh and disparate viewpoints which will result in benefit, not only to NIH programs, but also to the national understanding and the exercise of national responsibility. A tightening of requirements for reappointment would be consistent with current committee management practices at NIH, which are now based on a limitation prescribed by law. At the same time, such modifications should be kept in balance: undue restrictions upon membership could result in denying access to the experience of advisers familiar with the diversity of NIH missions, with the operation of this complex system, and with the officials whom they are advising. Consequently, the selection and appointment procedures for

National Advisory Council members are being revised to provide for special review of all recommendations for reappointments to assure that such reappointments are made only when there is clear evidence that the national interest is served thereby.

The selection and appointment of members of technical advisory committees present a different set of considerations. The maintenance or enhancement of ability to judge the scientific quality of proposals is paramount. Candidates for appointment are therefore selected primarily on the basis of outstanding qualifications as investigators in clinical or laboratory research. Because this review system is designed to assure the maintenance of scientific merit in the projects supported, it thus demands that its membership be selected on the basis of competence.

Thus, in respect to Part II of Recommendation No. 16, the Department must emphasize that the first requirement for selection of technical advisors is excellence in a specific field of research. Since excellence in science and medical research is not equivalently distributed in all States and all institutions, a proportionate representation in the distribution of PHS technical advisors by State and institutions cannot be expected. Inevitably the distribution of Federal support in mission programs follows the distribution of competence, which in turn forms the universe from which technical advisors must be selected. There appears to be no reasonable escape from this dilemma. To the maximum extent possible, the Department will endeavor to assure the broadest representation in the selection of technical advisors consistent with the basic obligation of serving the primary statutory objectives involved.

Institutional Accountability

"Recommendation No. 17.--The committee recommends that the percentage of grant funds allocated to the general research support program not be increased, and no new forms of institutional support be initiated, until (1) PHS has modified GRS policies for a more equitable and efficient distribution of these funds, as recommended earlier in this report, and (2) PHS or HEW is prepared to promulgate grants management standards and to determine that institutions wishing to be eligible for research support are in compliance with those standards."

Without question, the grant relationship imposes upon the grantee clear responsibility for the effective management of the funds awarded in the accomplishment of the purpose for which the grant was made. The statement of principles governing the use of grant funds by grantee organizations promulgated by PHS makes this fundamental condition clear. Thus the Department is in full concurrence with the objectives being sought in the committee's discussion of the problems of institutional accountability.

The matter of concern for the Department that arises in connection with the Committee's discussions of institutional accountability is the implication that the recipient of a grant, to meet the obligation for prudent management, is required as an absolute condition of support to give evidence of the existence within the grantee institution of formal management systems utilizing modern accounting and auditing, central purchasing, inventory management, and other basic business techniques. As the Committee is well aware, authority to make grants involves an explicit Act of Congress. Thus, the grant is viewed as a special instrument of public action. It is distinguishable from a contract in that it does not constitute the procurement of goods or services required for the performance of public business. In contrast, it is a unilateral act centered in the concept that the public interest will be served by contributing to the work of a non-Federal organization. Thus the primary concern in making a grant is the identification of the public value to be gained through the grant and the capability of the awardee to advance such value. The determination of whether the public interest has been so served is not in the nature of the expenditure that is made under the grant, but the degree to which the broad objective being sought has indeed been furthered by what was accomplished as a consequence of the award.

In respect to Recommendation No. 17, however, the Department is convinced that it would be unwise to establish any absolute degree of management capability on the part of a grantee institution as an explicit condition of eligibility for research support. This must continue to be a variable judgment encompassing both the nature of the public purpose to be served and the assessment of this Department of the capability of the institution for prudent use of the funds involved. This view, however, will not diminish the efforts of the Department and its constituents to contribute to the managerial capability of the framework of non-Federal institutions upon which the progress of its grant programs depends.

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